Governance Workgroup Public Hearing
Draft Transcript
September 28, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good morning, everybody, and welcome to the HIT Policy Committee's Governance Workgroup. Just a reminder, this is a federal advisory committee, which means the public will be able to ask questions at the close of the meeting, and a transcript of the meeting will be available on the ONC Website. A further reminder to members of the workgroup, if you would please identify yourselves when speaking for attribution. Let's go around the table now and introduce the members beginning on my left with Mary Jo Deering.

Mary Jo Deering – ONC – Senior Policy Advisor
Mary Jo Deering, Office of the National Coordinator.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Wes Rishel, Gartner.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
John Lumpkin, Robert Wood Johnson Foundation.

Laura Adams – Rhode Island Quality Institute – President & CEO
Laura Adams, Rhode Island Quality Institute.

Michael Matthews – MedVirginia – CEO
Michael Matthews, MedVirginia and chair of the NHIN coordinating committee.

Linda Fischetti – VHA – Chief Health Informatics Officer
Linda Fischetti, Department of Veterans Affairs.

John Glaser – Partners HealthCare System – VP & CIO
John Glaser, Siemens Health Services.

Deven McGraw – Center for Democracy & Technology – Director
Deven McGraw sitting in for Leslie Harris at the Center for Democracy and Technology.

Judy Sparrow – Office of the National Coordinator – Executive Director
We do have a few of the workgroup members who are caught in traffic. Let me just ask if any members are on the phone. With that, I'll turn it over to Dr. Lumpkin.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Good morning. My name is John Lumpkin. I'm with the Robert Wood Johnson Foundation, and I will be chairing today's session. I will remind members when they speak to identify themselves. We've gotten pretty used to that on a couple of phone calls that we've been on, so it's just helpful because not everyone is able to identify voices, particularly if you're trying to listen to it on a train, and I apologize for that session.

This is our hearing, our public hearing that we have for our governance update and the calls for governance mechanisms. The reason why we're all here is because of the HITECH Act, which calls for a governance mechanism direct at the National Coordinator for Health Information Technology to establish a governance mechanism for the National Health Information Network. Every time we say that, there's a

little bit of an asterisk, for those of you who may not be able to see the slides or not looking at them online in that the name for the National Health Information Network will be changed sometime this fall.

As a result of the charge by the HITECH, the Office of the National Coordinator will be issuing a proposed rulemaking, which would identify governance mechanisms. Critical to those governance mechanisms are that they engender trust, they assure effectiveness, they meet or exceed consumer expectations, and promote and facilitate the use of the National Health Information Network. I think our concern is, of course, that these mechanisms be robust enough to insure trust and, at the same time, allow adequate innovation within the system.

Just to get a couple of definitions out of the way, first for the National Health Information Network, it's a set of policies, standards, and services that enable the Internet to be used for secure and meaningful exchange of health information to improve health in healthcare. As David Blumenthal said, and I'll get to— For those of you who may not know, he's the National Coordinator for Health Information Technology. The private and secure health information exchange enables information to follow the patient when and where it's needed for better care. The federal government is working to enable a wide range of innovative and comprehensive approaches that will allow secure and meaningful exchange within an across states, but all of our efforts must be grounded in, and here's the key component, in a common foundation of standards, technical specifications, and policies. He goes on further to say, our efforts must also encourage trust amongst the participants and provide assurance to consumers about the security and privacy of their information. This foundation is the essence of the National Health Information Network.

What is governance, and why is it necessary? These are the definitions we're going to be working on, and as we go forward, we're going to be massaging these, as we move forward to issue our final report, which I'll talk about in a few minutes. Governance is the mechanisms or mechanism that insures that the necessary policy, standards, and services that enable the use of the Internet for secure and meaningful exchange of health information to improve health and healthcare are adequately and appropriately established, coordinated, overseen, and enforced.

The governance functions taken together must improve health while insuring public trust and enable interoperability while stimulating innovation, critical to insure trust and enable interoperability. At the same point, we don't want it so tight so early in our network that it stifles innovation. Trust and interoperability can only be achieved nationwide with the development of specified information policies, the adoption of some common technical approaches and standards, and the establishment of clear oversight and enforcement mechanisms.

In the current system, there's a patchwork of these elements that exists to varying levels and is developed and overseen by many different pubic and private bodies, creating overlap in some areas, and gaps in others. We believe this creates a barrier to the interoperability that will yield the results of health information being exchanged to insure that patients and their caregivers can have the appropriate conversations with the right information at the right time. Today's hearing will help the workgroup understand the range of experience, issues, needs, and opportunities for governance mechanisms for the National Health Information Network.

The charge to the workgroup is to draft a set of recommendations on the scope and process of governance for the National Health Information Network, including measures to insure accountability and oversight. While we're doing that, we look to provide recommendations to engender trust in a National Health Information Network—we'll call this the network—and promote and enable broader participation, to inform the development of a notice of proposed rulemaking, as the Feds call it NPRMs, and to provide comment on that NPRM when it's issued.

There are a set of members of this workgroup. This workgroup reports to the Health Information Technology Policy Committee, which is the FACA committee that advises the Office of the National Coordinator. As such, we are, as a workgroup, work under the FACA rules (Federal Advisory Commission Act) or something to that affect. The members of the committee are listed, and those of you

who are here know who you are. For those of you listening on the Web, you can look for the attributions in this slide.

Let's talk a little bit about the deliverables because this is where the rubber hits the road. We're having a hearing on September 28th, and just so that water doesn't flow too much under the bridge, we're going to do our initial recommendations to the policy committee on October 20th with final recommendations to be presented on November 19th. Subsequent to that, we're going to be holding hearings in 2011 on that notice of proposed rulemaking somewhere, we believe, in the second or third quarter of 2011. You can see on our timeline that it's a very tight timeline, but this is a critical aspect of moving forward, the network for exchanging health information to assure good health outcomes.

We're going to have a series of four panels, and these panels will be the first one, which will be on governance models and other domains. Then we'll have panels two and three where we'll be hearing from governance experience of implementers of health information exchange, particularly asking them to focus in on the issues of trust, interoperability, accountability, enforcement, and oversight, which is critical to insure trust. Then, finally, the fourth panel will look at some existing governance authorities that already exist that may have some influence over health information technology. We will follow that with some opportunity for the committee to have a discussion followed by public comment.

I do want to point out that we do have the meeting next Monday where we hope to take the results of the small subgroup that's been working on developing a preliminary recommendation for us to review to have at it, reminding you all that in just two short weeks or so after that meeting, we will have to issue at least our preliminary report to the policy committee. We will also be coordinating our activities with the policy and security tiger team. Because so much of what we're doing has overlap with them, we want to make sure that we're in synch and harmony with that effort that is also ongoing.

With that, do we have any questions before we move to the first panel? Great. Let's move on to the first panel. This is governance models in other domains with special relevance to health information exchange. We have two panelists this morning. We appreciate so much that you're willing to brave the humid weather and traffic in Washington, D.C.

Talking first about e-commerce, we have Mark MacCarthy from Georgetown University. He teaches and conducts research at Georgetown University of Communication, Culture, and Technology Program, and he has played an important role in developing governance procedures that are adopted throughout the e-commerce sector. For those of us who have credit cards, we appreciate the work that you've done.

The second speaker is from the National Quality Forum, Laura Miller, Senior Vice President and COO, previously served as interim executive director of the National e-Health Collaborative after many years at the VA. The National Quality Forum plays an important role in setting standards for measurement and reporting of quality information and is a public/private entity.

We'll start off with Mark.

Mark MacCarthy – Georgetown University – Adjunct Professor

As the chairman mentioned, I'm with Georgetown right now, but I was previously at BCIP for eight years where I handled issues relating to information security and new products and so on. I'm going to talk today—I'll describe some of the features of the U.S. retail payment industry that might be of use to you, as you think about a governance mechanism for National Health Information Exchange. I'm going to focus on two things. One is the development of the payment card industry data security standard, and the second is the development of standardization in the area of interoperability.

Let me summarize my major points as follows. First, a centralized security standard setting organization can help prevent industry fragmentation. I think, when you have a security program, you have to distinguish the various elements of it. There's a standard itself. There's the compliance with the standard and validation of compliance with the standard. Third, there's enforcement. You have to assign responsibilities to the different parties very carefully to know who is responsible for what.

In the area of enforcement, I think you might have to look for government, for enforcement in the area. Pay attention to liability rules. They can do a lot of good stuff. They can provide good incentives for security. They can promote innovation. They can protect customers or healthcare customers. And they can promote industry growth, but they can also bog an industry down in unproductive litigation.

On the interoperability area, we'll see that the payment card world did a pretty good job in developing interoperable standards. But they're a less fragmented industry than the one that you're dealing with. If there's a public policy in interoperability, there may need to be a government role to coordinate the development of interoperable standards.

Let me start for a variety of reasons, which I can talk about in more detail later, the security incentives in the payment card world are not ideal from the point of view of just allowing the marketplace to function. For that reason, the industry in the late 1990's began to look at developing a standard for keeping information, cardholder information safe and secure. In 2001, Visa developed what they called their cardholder information security standard. A couple of years later, MasterCard had a similar standard, but for the first several years of their life, these standards were separate and independent operations, which created a difficulty for obtaining compliance from merchants in the area.

In 2004, several years after the standards were actually developed, they were aligned. Visa and MasterCard put together their standards, and it took two years after that for an independent security standard organization to be formed. The Security Standards Council was formed with an executive committee consisting of the five major payment card brands, and they've guided the development of the standard ever since. That's the governing body of the standards development.

Let me talk quickly about the standard itself. It's got 12 very general rules backed up by a large number of very specific requirements. It is the kind of standard that goes beyond guidance. You can assess compliance with it. You know when someone is in compliance with the standard and when someone is not. One of the rules, for example is don't save the cardholder security codes. You can check in a computer system to know whether or not that security code had been saved.

In addition to the standard itself, there's a process called validation where merchants and processors have to demonstrate that they're actually in compliance with the standard. They do that by getting an outside assessment from a qualified security assessor, and they have quarterly scans done by an approved scan vendor. Those outside entities, the scan vendors, and the security assessors are vetted and approved by the security council so that there's no way in which an entity can claim to be in compliance if he hasn't used one of the approved vendors.

Enforcement: Enforcement is not done by the Standards Council. Enforcement is in the hands of the various payment networks, the Visa, MasterCard, American Express, and so on. The best way to illustrate this is through an example. In 2004, a major processor, CSSI, had a serious breach. They were egregiously out of compliance with the industry standard. The different payment networks responded differently. Visa said this is too egregious. We're suspending you from the system. MasterCard did not. American Express did. So the role of standards is under the control of the Standards Council. The validation is the kind of thing that is directed by the council, but enforcement is in the hands of the payment networks themselves.

How good is enforcement? The private sector is doing pretty well at getting enforcement in that key area of not saving a security code. Among the largest merchants, compliance is about 100%. Among the smaller merchants, they're less successful. But there have been some difficulties in enforcement. There have been large-scale data breaches. When that happens, the Visa and the MasterCard systems try to take some of the costs associated with those breaches and move them back to the merchant or processor who was responsible for the breach itself. That's done in private sector cost allocation techniques.

In addition, there are court cases. Some of the financial institutions who suffer losses have gone to court to try to recover some of the damages. They've largely been unsuccessful, but Visa and MasterCard have tried to negotiate settlements with the breached entities that will provide some cost recovery in that area.

There are mandates from some states. Minnesota has a rule that says you have to be in compliance with certain elements of the PCI standard. If you're not and you suffer a data breach, then the cost associated with that data breach is your responsibility. Those cost recovery statutes give a standing to the community banks and the other banks to go into court to try to recover the costs. I'm a little worried about that technique since I think it might just create a series of litigation efforts that might not be productive. That's the PCI situation.

Two seconds on the standardization: Back in the late 1960's when the industry was just getting started; they realized that electronification was the way to go. So they worked with ANSI (the American National Standards Institute) to develop a series of standards: One for the numbers that go on a credit card and what goes in which place in that number, and also on the physical size of the card. Those standards were eventually brought into the international context. ISO adopted standards that reflect that, so the whole system is internationally interoperable.

One of the big advantages of this is merchant acceptance. If you don't have that kind of interoperability, then merchants are in the situation like the early telephone industry where you have to have two telephones on your desk to talk to everybody, and so it makes it much easier if you've got common standards to get merchants to accept this. In addition, there was an incentive in terms of the discount for what the merchants had to pay for the use of the card if they used the electronic system.

Other advantages of interoperability, it makes entry into the marketplace easier. When Discover came into the marketplace in the mid 1980's there was already an established standard that they could work with. They didn't have to come in and invent their own way of doing things. They simply built their system to the existing standard.

A couple of other examples of the industry standardization, chip and PIN, the system that's used in most other parts of the country. In 1999, Europay, MasterCard, and Visa worked together to set standards, the EMV standard, which governs the use of chip and PIN worldwide. In the United States, when the contactless cards were introduced in 2005 or so, Visa, MasterCard, and American Express all independently adopted the same ISO standard for communicating between the card and the new terminals, so standardization has been relatively successful in the industry, avoiding the kind of fragmentation that can prevent the growth of the market.

But it seems to me that one of the major elements of the success is the fact that it is a relatively concentrated market. There are a limited number of players. They can work together. There's a real national interest in interoperability, and you're dealing with a very fragmented market. It might be useful to have the government play a more active, coordinating role to achieve that purpose. That's my testimony. I'd be happy to answer any questions and engage in discussion with the panel and others.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We'll take some testimony from Laura and then we'll have questions for both panelists.

Laura Miller – National Quality Forum – Senior Vice President & COO
Good morning, Mr. Chairman and members of the workgroup. I'm very pleased to be here representing the National Quality Forum and able to provide you hopefully some insights into, as you say, governance in another domain.

The history of NQF goes back to 1997 when the President appointed an advisory commission on consumer protection and quality in the healthcare industry. In its final report, the commission concluded that an organization like National Quality forum was needed to promote and insure patient protections and healthcare quality through measurement and public reporting. As a result of the commission's

recommendation, a group of public and private individuals coalesce to identify a path forward, which resulted in the incorporation of NQF as a private sector 501-C3 organization in May of 1999.

The original mission was primarily to serve as national standards setting organization for performance measures, but in 2007, that was expanded to identifying national priorities and goals for quality improvement and promoting the attainment of those goals through education and outreach. In the area of priority setting, NQF carries out its work by serving as a neutral convener of a multi-stakeholder partnership, the National Priorities Partnership, and I'll speak more about that in a minute.

In carrying out its standards setting responsibilities, NQF adheres to the requirements of the National Technology Transfer and Advancement Act for private sector standard setting organizations. NQF's work is overseen by a board of directors who have a specific focus on strategy, but who also, of course, perform the important fiduciary duties that are the responsibility of a board. The board is comprised of 32 voting directors spanning the entire healthcare enterprise.

Four directors are from the federal government. Those are from CMS, AHRQ, HURSA, and CDC. The NQF president, Janet Corrigan, serves ex-officio and, in addition, there are three ex-officio nonvoting directors who are liaisons from NFQ's three major standing committees, and each member of the board serves a three-year term with a rotation. Very important to us distinguishing characteristics of the NQF board is that consumers and payers who purchase services on behalf of consumers are a simple majority of the at large board seats. We believe that a strong consumer voice is important on meeting the information needs of consumers and patients.

In 2007, the NQF board gave approval for NQF to convene a new entity, a partnership of public and private sector healthcare leaders who cross healthcare and have significant influence over healthcare in the American scene. Today the partnership consists of 42 organizational partners and 6 ex-officio nonvoting federal partners. While the NQF board had the responsibility for appointing the partnership members based on a public nomination process, and have the responsibility to insure the integrity of the process of the partnership, the recommendations and the activities do not come to the board for ratification. This is unlike the consensus development process for performance measures, which do come to the board for ratification. I wanted to note with appreciation that the Robert Wood Johnson Foundation has been a significant source of support for the national priorities partnership.

The board has designated three standing committees. One of those, the consensus standards approval committee, has oversight of the consensus standard development process recommendations. There is a health information technology advisory committee, fairly new, just established as a standing board committee within the last year, and the leadership network, which has responsibilities for the education and outreach programs. Membership is a very important component of our organization. We have 427 members representing the full spectrum of healthcare organizations, and each member organization is assigned to one of eight member councils, which serve as a forum for discussion and input into NQF activities. I won't go through each of those councils. They are listed in the transcript of my testimony, which was provided to you.

A note on funding: NQF receives about half of its funding from the federal government, about 15% from private foundations, and about another 35% from membership dues. The Robert Wood Johnson Foundation has and continues to play a particularly important role and provided startup funding, as well as some funding for organizational infrastructure and specific projects. The Centers for Medicaid and Medicare Services and the Agency for Healthcare Research and Quality have also been important federal partners providing project specific grants and contracts over the years.

You, in your questions, raise the issue of what is the government authority and what authorities have been granted to the organization. The organization of the National Quality Forum is a private sector organization, but the government relationship is important in terms of contract specifications for the work that they wish to have accomplished by our organization. In 2009, the U.S. Department of Health and Human Services awarded a contract to help establish a portfolio of quality and efficiency measures that

will allow the government to see more clearly how healthcare spending is achieving results for patients and taxpayers.

The contract was part of a provision in the Medicare Improvements for Patients and Providers Act that directed the secretary to contract with a consensus-based entity such as the National Quality Forum. The contract provided $10 million for 2009, was renewed in 2010, and has the option for renewal through 2012. The contract is administered by ASPE, the Assistant Secretary for Planning and Evaluation, and is a first for us, NQF, the oversight of that contract has included a GAO audit during this last year with a promise of another during the next phase of the contract.

NQF uses a formal consensus development process to evaluate and endorse consensus standards and has been carefully designed to assure integrity and transparency. Because we use this process, we are recognized as a voluntary consensus standard organization. As you know, the Act requires federal agencies use privately developed standards when they are developed according to the requirements within the Act in OMB circular A1-19.

We use a number of steps in our organization to assure multi-stakeholder input, and those are listed in the testimony. I won't go through them all, but just to highlight that every step along the way from public calls for membership and all project committees and technical advisory panels to a final posting of all documents, comments, public comments on our Website, assures the availability of all of the processes to the public and also to those who have a particular interest in any specific issue. The use of our Website in order to accomplish this task plays an integral part in the availability of the information. There is timely posting of information for every project. Individual, customizable dashboards are available. And the Web is used for making comments by the public on project outputs. We also have other communication tools that reach out to our members and to the public.

As part of developing the trust fabric surrounding the consensus standards activities, we pay particular attention to committee appointments and to disclosures of interest. Council reviews each committee nominee disclosure. Each meeting includes opportunities for disclosure of interests. Each steering committee is comprised to assure both consumer and purchaser representation, and members are selected to assure balance of interest with additional consideration based on the specific needs and technical requirements for any particular project. As well, when necessary, we reach out to the broader healthcare community to fill the needs for a particular perspective or area of expertise or to assure a balance of interest. That concludes my prepared testimony, and I'm happy to answer any questions that you may have.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We have about half an hour for questions. Mike?

Michael Matthews – MedVirginia – CEO
Thank you both very much for those insightful comments. I'd like to direct the first question to Mark. Certainly your insights and learnings are useful to this body and where we are in the healthcare space. I'm not as interested in how you got to where you are as I am in where you got to.

In other words, when you were at a similar point in development, say 15 or 20 years ago, and you were looking forward with some of the challenges that you had in terms of standards and interoperability and acceptance in the industry, how clear cut was it at that point? What needed to be done? How are you going to do it? In the rearview mirror, everything looks very orderly of what you presented today, but looking for this body, as we are in a bit of more speculative about some of the issues, how did you deal with the engagement of stakeholders and so forth?

Mark MacCarthy – Georgetown University – Adjunct Professor
That's a tough question, but let me just speculate a little bit with you to give you a sense of the alternatives that the system faced. Let's think about the security issue, and that's one. In the late 1990's, it was clear that the good incentives for security were not quite working. I mean, the put the liability for unauthorized use not on the cardholder, but somewhere on the financial institutions. But the way liability

was allocated within the institutions meant that if a merchant or processor didn't do good security, they weren't liable for the resulting losses.

You really had two choices at that point. One was to make the information that the merchant and the processor had less valuable, so you go in the direction of chip and PIN, which makes the information less valuable. Or you develop a security standard that says here's what has to be done to keep the information safe and secure, so that's almost a technical decision, but not quite because of the economics involved in both of those two directions.

Once you decide to go in the direction of standards, there was difficulty within the industry, even though it only had four major players in reaching a consensus on what the standards would be. What you found was that Visa and MasterCard took the lead, and they developed standards that were close, but not quite aligned. It took a period of several years before the difficulties of having that kind of fragmented approach became crystal clear. The merchants were not complying, despite requirements to do so, simply because it was too difficulty to try to comply with separate validation requirements, and so you move from that to an aligned system.

That gives you some flavor of some of the difficulties that we were faced with at the time. Then the move from there to a centralized standard setting operation was a logical step. It just took a couple of years to get to that point. If you've got an aligned standard, it shouldn't be owned by any one of the participants. It should be something that the industry as a whole has a say in. It shouldn't be the property of any one of the industry participants. Movement to a separate and independent standards development council became the logical way to go.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I'm remiss. We actually have three members who have joined us since we started, so if I could just ask them to introduce themselves, maybe starting with John.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
John Mattison, Kaiser Permanente.

Christine Bechtel – National Partnership for Women & Families – VP
Christine Bechtel, National Partnership for Women and Families.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Carol Diamond with Markle.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Did you have a followup question? As Linda has suggested, if you do have comments, it would help me if you would put your nametag up, so I can keep a queue. Linda?

Linda Fischetti – VHA – Chief Health Informatics Officer
Thank you both for the excellent testimony. To my fellow colleagues on the committee, I heard a note in there presentation that you may not have heard, and I just wanted to emphasize that ISO, ANSI were both mentioned by Mark. Laura talked about the attributes of the consensus-based standards development environment within NQF. Within the U.S. federal government, we are unable to participate in any standards development organizations that do not have, for example, the strict accreditation that ANSI does have and that ANSI actually provides for other organizations such as HL-7 for that open consensus-based standards organization. We have that in our testimony.

It's very pleasing to me for both of you to come forward with examples of success that do have the attributes of a governance organization, which actually I know in NQF's situation was developed specifically to allow for federal participation. I just wanted to make sure that that was emphasized here and allow Mark and Laura the opportunity to speak to advantages, disadvantages of either that governance structure or U.S. federal government participation.

Laura Miller – National Quality Forum – Senior Vice President & COO
I think it's critical for NQF that we do have ongoing government participation, strong participation from CMS, from AHRQ and, as you said, our structure allows that. It's important that it be private/public sector given the nature of healthcare, given the public sector funding in healthcare. I might add that one of the important issues for NQF now is to think about ways of reaching out more broadly to assure, although we have some state and local level participation. It's important, given the future of growth in some of those areas with health information exchanges, that we reach out further in that arena.

Mark MacCarthy – Georgetown University – Adjunct Professor
Yes. I do think that some government participation has to be found in this area. It was present to some degree in the payment card word, more so in Europe than in the United States. The European movement to chip and PIN was clearly guided by the banking regulators. They effectively brought the payment card world into a room and said, we should all move to chip and PIN, shouldn't we? Then with the regulators' approval, the various incentive system was developed to move the industry and the merchants to that kind of system.

In the United States, there's a less directive role, but there's still some. The banking industry is heavily regulated, so when there was some concern about phishing attacks on people's online banking accounts, the federal regulators were able to step in and say, we're going to be examining you, banks, for compliance with your requirement to keep information safe and secure, and maybe you should think about doing two-factor authentication instead of the old single factor. That intervention moved large numbers of the financial world into a more secure kind of system. Something like that, I think, is going to be needed in the payment world and, I think, in the world that you're looking at, some affirmative role for government to coordinate the upgrades of standards, I think, has to be something that's on the horizon.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Just if I could backtrack a little bit, Mark, chip and PIN?

Mark MacCarthy – Georgetown University – Adjunct Professor
Chip and PIN is a technology that incorporates a computer processor on a payment card. That's the key factor, and so when the card is read by a reader, there's an interaction between the information on the card and the reader itself. What that provides, among other things, is the capacity to generate a new authentication code every single time, and it makes it much more secure. There are other advantages, but the big advantage is that security advantage.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I find that if I miss a meeting in the health information technology word, I don't understand the acronyms anymore. In another field it's also challenging. Laura?

Laura Adams – Rhode Island Quality Institute – President & CEO
Thanks also to the both of you for the testimony. It is very enlightening and thought provoking. I'm going to direct this question to you, Mark. It was a very, very interesting element in your written testimony talking about a crucial fact about the U.S. retail payment system is the network architecture is centralized. Then you go on to say in your written testimony that the network operator has control over processes and operations of the system in such a way that significant innovation can occur only from the center.

You close out that paragraph by saying this general fact about the U.S. payment system is a network means that information security innovations must be orchestrated and guided by the system operator. I just want to validate an assumption that we are not to take away that innovation is stifled by the design of that system. That certain elements of that system are centralized and standardized, but it does not preclude innovation in many ways.

Mark MacCarthy – Georgetown University – Adjunct Professor
I think that's right. I mean, we're all very comfortable with the idea of innovation in an end-to-end system like the Internet where everything is decentralized, and so there are thousands or millions of people at the edges, all of whom are innovating like crazy. That is certainly one model for innovation. But what I'm

suggesting is that in these kinds of centralized systems, with the right sort of incentives—for example if the liability for an unauthorized use for fraud is placed somewhere within the financial institutions that are involved in the payment network—they have the incentive to innovate at that point.

Over time, you saw in the payment world the fraud rate drop from 20 basis points in the early 1980's to around 5 basis points around 2002, 2003, all as a result of enormous innovation in neuro-networks and the development of security codes and other antifraud mechanisms, all of which were orchestrated centrally. So there are huge incentives in that system for innovation, but you have to be careful how you design a system like that to make sure that the incentives are set up right. It doesn't happen automatically. One of the advantages of the end-to-end system is that if you just let people do whatever they want at the ends, a lot of people will come up with interesting and clever things. The centralized systems need the right sort of incentives to make sure that they have the push to move in an innovative direction.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Just to reorient myself to this discussion, I've been thinking that we're talking here about standards and policies on the one side, and creation, certification, and enforcement on the other side. Whether you think of something as a technical standard or an operating guide policy, in either case the same three questions apply to it. Does that seem consistent with your view of governance in your world?

Mark MacCarthy – Georgetown University – Adjunct Professor
In my world, yes. I think that's it. You've got the standard. You've got the validation of compliance. You've got enforcement, and then you've got to watch out for liability. If something goes wrong, who pays the bill? Those are the elements.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Liability is either, first of all, it starts with an understanding of the law, and then from there it is in the construction of agreements that are signed in order to participate in the network. Stop me if I'm wrong.

Mark MacCarthy – Georgetown University – Adjunct Professor
That's absolutely correct. The way liability works in the payment card world is partially through government mandates with the Feds negatively. Cardholders are not liable for unauthorized use. Then affirmatively, it's done through contracts at different payment networks engaging with their members.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Is that contract uniform with all participants in the networks?

Mark MacCarthy – Georgetown University – Adjunct Professor
The Visa contracts are uniform. The MasterCard contracts are uniform, but they're uniform within their systems. No one outside of the Visa system dictates the contract that Visa uses. Visa does that. MasterCard does it as well.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Arguably, there are similarities between Visa and MasterCard, but they're not identical, and there's no governance attempts to make that actual contract a standard contract.

Mark MacCarthy – Georgetown University – Adjunct Professor
That's right. That's why, for example, the enforcement is left up to the individual entities. That's a matter of their contractual relationship with the financial institutions that are part of their systems.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I want to make it absolutely clear to everyone how completely ignorant I am of this, but what is the

financial network? Is that a corporation? Is that a bank? Does it invest the money that flows through it or just take a fee or what?

Mark MacCarthy – Georgetown University – Adjunct Professor
There are two different kinds of systems within the payment card world. One is the one, American Express is just a single company. They issue their own cards. They work with the merchants. They're a centralized, single system all by themselves. They employ 50,000, 60,000, 70,000 people to handle all those relationships.

Visa and MasterCard are different. They started off as joint ventures, and they recently were spun off into separate companies. But what they do is they create a network of contracts with separate, independent financial institutions, 14,000 for the Visa system in the United States. Then those entities reach out to the cardholders who number in the hundreds of thousands and millions, and reach out to the merchants.

There are six million merchants within the Visa system. So you've got a distributed system where a lot of the responsibility for implementing decisions is distributed to the edges. But within the system itself, it's directed by the contracts that Visa and MasterCard set up. I don't know if that sort of clarifies it for you, but that's the basic outline of the system.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
It explains why I have so much trouble getting help on my MasterCard. I'm trying to relate that to healthcare. One of the assumptions we have not made in healthcare is that there are a few—count them on one hand—number of network operators that somehow include— You've already implied that that seems like a difference to you. Can you elaborate a little bit on how that difference would play out in establishing a network? I guess maybe you might also comment on the dollar loss in a financial transaction is completely known, and you can make a complete business decision about whether just to write it off or pursue it and so forth where the loss of healthcare information is of high concern, but not directly priceable. How does that impact the work we have to do?

Mark MacCarthy – Georgetown University – Adjunct Professor
On the first question, I think, as I mentioned, there are substantial differences. I don't know the healthcare industry and the network exchange part of the businesses as well as you guys might, so I can't speak to the precise differences. But two things jump out at me. One is that in the payment card world, there are two entities, Visa and MasterCard, that themselves have a function of integrating large numbers of different players.

Then there are only a small number of those players themselves, so you only have four major payment players in the U.S. retail payment industry, even though you're integrating large numbers of different entities, 14,000 financial institutions, 6 million merchants. I don't see that there's anything like that in the health information exchange area that can reduce the complexity through an internal system of contracts. That's the one contract that seems to be important to me.

The other about quantification, there is a substantial element of quantification in the financial services world. This is the fraud loss. You know what it is. But there's a substantial intangible element as well that's harder to quantify. If there's a loss of trust in a financial institution, they can leave. One of the reasons many of the community banks were so upset by security breaches is that they would get calls from their customers that said what did you do? I'm leaving. I'm taking my money. I'm going somewhere else. How much of that there might be is harder to put your finger on.

It's harder to put your finger on the loss of trust that would make people say I'm not using my card. It's harder to quantify those. They're there. They're real. But it's hard to quantify.

In the healthcare world, the danger isn't so much that people will suffer a financial loss, although there might be that. I think the real danger there is that people will simply not get the care that they need. People will say, it's too dangerous to entrust my information to the system. It'll leak out. It'll adversely affect me in employment or insurance or credit scores or some other way. If I'm not comfortable that the

information is safe, I won't reveal it, and if I don't reveal it, then I don't get the care that I need. I think it's a different danger on your side, but I think it's got the intangibility that some elements of the payment card world had as well.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
John? Of course, I have to be careful now. I think it's been a long time since I've been on a committee with this many Johns and John Houston isn't even here.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
First of all, I want to thank you for your excellent testimony, and the written testimony is particularly articulate and poignant. One of the things that you highlighted in the written testimony is the need to align the financial liability with the causes of breaches, so there are some self-corrective mechanisms and feedback loops. My own sort of framework for looking at how a system works or doesn't work goes straight to the alignment of incentives of what you're actually after.

In your written testimony, you did mention major audits that occurred with a major breach, got to the root cause, identified problems in security practices that were clearly ... and that's a great case study. You did also mention today that you reduced fraud from 20 basis points to 5 basis points. I'm sure that those kinds of audits and corrective actions helped bring it down.

You have six million merchants, each of whom could be accountable for one of these breaches, but doesn't have the direct liability. There's some indirect liability such as customers walking with their feet. In healthcare, I think it is quite a bit different that people are much less inclined to leave a doctor they've been with for ten years because their institution might have suffered a breach for some unclear reasons.

My question to you is, how well do you think the financial liability today in the financial world and its alignment with the source of breaches can be paralleled in healthcare where, as we already discovered, there's much more complexity, much less of a hierarchy of entities.? I'm curious what your thoughts are on that. It's a big concern of mine.

Mark MacCarthy – Georgetown University – Adjunct Professor
I'm not sure that the financial liability is perfect in the payment world even now. There are two dangers. One is you give people who need to do something to protect information a free pass, so they feel as if though they don't really have to do anything. But the other danger is creating liability, which then just creates a lot of unproductive litigation.

In the payment card world, if you just said anybody who loses information has to pay the costs associated with that, you could wind up with the following dialog from the breached entity. "What breach? I didn't do anything. Prove to me there was a breach." Someone proves that there's a breach. "Well, it wasn't my fault. It was the processor's fault." So it would have to be proven that it was this person rather than the processor.

Then you say, "Well, here's the cost associated with the breach." He says, "Well, it wasn't associated with my breach. There were ten other places where this information was compromised. How do you know it came from me?" Then you say, "Okay. It came from you." "Why is there a cost associated with the breach? Why didn't you, instead of reissuing all the cards at $25 a card, why didn't you just put them on a watch list and wait to see if there was any fraud?"

You get mounds of unproductive litigation where if the dollar value is high enough, people will simply say, "I'll call my lawyers, and we'll see you in court." So you've got to be careful about assigning liability in the fashion that just mires the entire system down in unproductive litigation. Where that balance is struck, I'm not sure I've got a good answer for you. But that's the balance that I think you have to look at.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Have there been discussions around enhancing the traceability of transactions so that the cost of discovery and establishing culpability are lower?

Mark MacCarthy – Georgetown University – Adjunct Professor
There are some discussions in that area, and as long as the dollar values aren't crazy, the sort of informal way in which the Visa and MasterCard system assign liability sort of work so that $50 million settlement that I mentioned with TJX that made the community banks reasonably happy, that was rough justice. You didn't try to trace the details of it. You just said, let's get something that makes everybody reasonably happy. I think that system has to be refined, and I think there has to be some sort of government oversight of it to make it work properly. But I don't think you're ever going to get to a situation where you can, with precise accuracy, trace this cost to this breach.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
I'll just extend my thanks to both of you also for your testimony. I have a quick question for Laura and then, unfortunately, Mark, a more complicated one for you. Laura, it's helpful to sort of have an understanding of the funding. Does funding come with any governance requirements? In other words, do funders have any governance requirements within the organization?

Laura Miller – National Quality Forum – Senior Vice President & COO
The only requirements that come with the funding really are outlined in the contractual documents in terms of the tasks, the expectations, statements of work, reports, etc. There is not a specific governance requirement in the work itself.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
There's no governance rule on the part of the funders in the organization?

Laura Miller – National Quality Forum – Senior Vice President & COO
Not per se, no. There is, as I mentioned, participation by CMS and AHRQ and CDC and HRSA on our board, and certainly participation in meetings, processes, etc.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Mark, great information, and actually I think the Q&A has been very instructive. I'm going to go a little bit where Wes was going, which is to sort of try to give us some perspective on where this fits in the problem we're trying to solve. It's very tempting for many of us to zone right in on the security standard or the network, but our task is really to think about the governance. Although these are common problems in the two areas, security is one layer, if you will, or one element of a broader array of tools that someone would bring to bear on sort of providing trust.

You've alluded to some of these other layers in your answers actually in the Q&A, sort of the rules that all financial institutions have to play by and where they come from and where enforcement comes from and where the policy setting has come from. Can you sort of give us some kind of a contextual framework for how you see this one security piece of trust fitting into that broader milieu? My feeling is if, for instance, the cardholder was liable for the breaches, it wouldn't matter what the network did. Customers wouldn't use it, right? They'd be afraid to use it and be afraid to use their card. I'm wondering if you have or can give us sort of a broader frame for how you see the elements that make this work from a governance perspective.

Mark MacCarthy – Georgetown University – Adjunct Professor
I think the key thing that helps both trust and innovation in this area is the structure that I outlined earlier, which is, you have a standard setting organization itself, which is industry-wide. I do think if you try to have just sort of independent entities trying to make up their own ways of doing things, you will fragment. That's what happened in the Visa and MasterCard example for the first two years of the system. There was not a complete incompatibility, but a significant lack of alignment. The way to fix that, you could just sort of say let's all work together, and you don't have to have a separate organization.

But what the industry found is that it made sense to create a separate organization. Then you've got a framework where, as you look to improve things, because no security standard is permanent, you've got a centralized place where you can go to and say, let's talk about what we do next, and that's going on right now. Do we do end-to-end encryption? Do we move the chip and PIN? What do we do? There's a mechanism whereby the industry can have those discussions, so a centralized standards setting operation is really kind of crucial.

Then there's the standard itself, which has to be developed. Mechanisms for how you validate compliance, I think that second step is really crucial. It is not enough to say here's a standard. Go forth and do good. You have to have a mechanism whereby people who are supposed to live up to that standard have to demonstrate it. It's the second step, have to demonstrate that they're actually in compliance with the standard. That second step, I think, is crucial. That can be done in a centralized fashion as well.

The mechanism that worked there was one that said you can't just sort of say you're in compliance. You've got to get someone outside of your organization to say you're in compliance. So who are those people? The standard setting organization went through a vetting process and said here are the people you can use to demonstrate that you're in compliance. That step, I think, is crucial.

Then the enforcement, if something goes wrong, what's the process for enforcing the standard when someone has not been in compliance and there's been a data breach. What do you do? That's, in the Visa and MasterCard system, that's distributed. I don't see how to centralize that in any circumstance. There are just too many actors involved. I do think that that's a stage where you might need some centralization from government, so the government can look at that situation and say, let's take some action.

I didn't mention this. The Federal Trade Commission had 15 to 20 cases against merchants who had been involved in data breaches where they said you're guilty of an unfair trade practice because you didn't engage in reasonable security. What's reasonable? The PCI standard was, in effect, their touchstone of reasonable security practices. That's a step in the right direction. It turns out the FTC can't levy fines, so there was no financial penalty for this. But it got the government involved in trying to enforce the standard, and I think that's a good step. Then, finally, the liability stuff has got to be made clear. You've got to know who pays if there's actual damage, measurable damage.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Can I just ask a followup? Then I think Wes asked this question too. Can you just remind everybody how the fees work in the network between merchant and network?

Mark MacCarthy – Georgetown University – Adjunct Professor
There's a fee that every merchant pays for the use of the card. It's a percentage of the transaction. In the Visa system, it's about 2.5% of the transaction. American Express is a little bit higher. A substantial portion of that fee goes through the network system and goes to the issuing bank. It's called the interchange fee. Some of it stays with the bank that works with their merchant, and some of it goes to the Visa system to defray the cost of operating the centralized system, so that's roughly how that system works.

What you can do is you can manipulate that number, that percentage for various purposes. For the electronification of the payment card network, that was the fee that was manipulated to encourage merchants to adopt the electronic terminals. There are other ways of manipulating that number, but that's one that would provide a very serious incentive for people to do things properly.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research

My question is for Mark as well. I'm interested in the areas of compliance and enforcement. I've been really interested in the conversation about liability because I think it could be a really helpful tool, and hearing your concerns about it also can be troubling if it's done poorly.

I have a couple questions. One, I'm wondering, in the financial industry, how the liability developed. How much of it was the industry sort of coming up with their own rules and then the government intervening when there was a problem, versus the government sort of taking a lead role in establishing liability? I'm interested in how that developed.

The other question I have is a very short one, which is, I just want to make sure I understood what you said correctly about the FTC. The FTC, under their authority, was basically enforcing the privately developed security standards. Is that accurate?

Mark MacCarthy – Georgetown University – Adjunct Professor
Yes. Let me answer that last one right, first. Under their authority, they have authority to take action against unfair practices, so what's unfair, they determined that when merchants didn't engage in reasonable security precautions, they were involved in an unfair action. What's reasonable? They had no way of independently determining that, but there was a standard that had been developed in the industry. They didn't refer to the standard in their decisions. They just listed the infractions that their merchants had been involved in.

If you look down the list of infractions, they matched up pretty closely with the standards that were involved in the PCI standards. So saving the security code, for example, was often mentioned as a problem, and that's one of the things that's allowed under the PCI standard. It wasn't that they picked up the standard and established it in their decisions. They just looked to the standard as a way of defining what a reasonable level security would be, so that's how that happened.

On the liability, the government was involved early on. Well, back in the 1970's when the system was just getting up and going, there was a question. What do you do about unauthorized use? If you'd left it up to the industry at that point, they would have left the liability on the cardholder because it would have minimized their short-term losses, and so congress looked at that said that's not fair. What they did is they said, whatever you do, you can't put that liability on the cardholder. There was a $50 maximum for unauthorized use that they put in place in the statute.

What that wound up doing over time was two things. It provided for enormous consumer trust that people would now realize that if they used their card, and someone got hold of it and used it for improper purposes, they wouldn't be liable for more than $50 for the fraud involved, so it gave enormous trust. That in turn created enormous growth in the industry. It really had a very good affect on the industry as a whole.

The second thing it did is it created enormous incentives for the financial system as a whole to engage in good security. They had to develop the antifraud measures because, if they didn't, they bore the losses. It's that that produced the investments in neuro-networks and security codes and so on that, over time, reduced the fraud rate from 20 basis points to about 5 basis points.

Going back to the point that you made before, that long-term decline was before the current series of data breaches. That sort of leveled out—the data breaches that hit the payment world in the mid 2000's basically brought that long-term secular decline in fraud rates to a halt. It was on the way down, and it stalled at about five or six basis points. But it doesn't change the good results of that liability rule.

This may not have been intentional, but when we were designing a new system, it might be intentional. They found the place in the system where the entity could innovate to solve the problem. They found the payment network, right, and said you can fix the problem.

Going back to your point about how it's a centralized system. They found that point and said you've got the liability. If you don't fix it, you've got to bear the cost. So when you're thinking about a security

system and thinking about a way to make it work over time, the key thing to do is find the place where people can innovate to solve the security problems. In the financial networks, it's the financial centralized network that's not at the edges. You put the liability on the individual consumer, and they're going to shrug and say, I can't figure out how to solve this problem. But the networks can.

Christine Bechtel – National Partnership for Women & Families – VP
I have a comment for Laura, and I've got two questions for Mark. Laura, I just want to say that from a consumer perspective, we're really delighted with the work that NQF has done to make sure that consumers and purchasers have a very robust voice in the process. I know that it wasn't always the case, and NQF has really done a terrific amount of work over the last number of years to make sure that consumers in particular are not just sitting at the table, but completely outgunned and outnumbered by the provider and other interests, but really have a meaningful opportunity to shape the decisions and the direction of NQF, so I think that's a terrific thing.

Mark, Wes actually asked a couple of my questions, which frankly makes me feel smart already, but I just have one quick followup. The folks who operate the payment architectures—is that then American Express, MasterCard, Discover, Visa?

Mark MacCarthy – Georgetown University – Adjunct Professor
Yes.

Christine Bechtel – National Partnership for Women & Families – VP
Those are the four key players that you talked about. When we think about policy decisions that are made, one of the things that you talked about in your testimony was the fact that federal law limits liability, which I think it's $50 or $500 in some cases on debit, but that the industry practice is really zero. That's a policy decision, and what I want to ask is sort of how those decisions come to be about and whether there's public input into them. But I want to give you the context in which I'm really thinking about that because that's a fairly simple and straightforward policy.

The context that I'm thinking about is other uses of data, and so in your case, other uses of financial data. That's really the second question that I have. The second question is really, do network operators use financial data other than for payment purposes to do trending and analysis of consumer buying habits or I have no idea what? If so, who sets the policies around how they're allowed to use and disclose that data.

Mark MacCarthy – Georgetown University – Adjunct Professor
You're shifting to basically the privacy issue because that has to do with now the information is in the system. Who can do what with it with what kind of consent? There are federal laws that regulate that. The Gramm-Leach-Bliley Act from 1999 set out very general principles about what can be done with the information. It's essentially a notice and choice regime where the financial institutions have to tell their customers what information they've got, what they want to do with it and, in some cases, get consent. So it's a notice and choice regime.

American Express has complete control over the information there. As I mentioned, they are a centralized system, so they have all of it, and they can decide what uses they want to make of it. The Visa and MasterCard system of the information is basically decentralized to the edges, so it's the financial institution that you get your card from that has the decision about to do with the information. They're regulated by Gramm-Leach-Bliley.

If they're going to do something with it, they're going to turn it over, for example, to a third party marketer. They have to give you a statement that they intend to do that and give you an opportunity to opt out of it. Those are the privacy notices that many of you have been getting from your financial institutions for the last seven or eight years. They're supposed to disclose that kind of information.

Christine Bechtel – National Partnership for Women & Families – VP
I'm guessing, based on your answer, just to clarify, that American Express may solely control the data, and I think that's certainly the case in healthcare. But there are opportunities often for the public or

consumers to weigh in and say, this is an okay use, this isn't an okay use, to inform that company's particular policy.

Mark MacCarthy – Georgetown University – Adjunct Professor
Yes.

Christine Bechtel – National Partnership for Women & Families – VP
So what I'm hearing you say is probably there isn't that practice in the industry. Is that correct?

Mark MacCarthy – Georgetown University – Adjunct Professor
Isn't what practice?

Christine Bechtel – National Partnership for Women & Families – VP
Having some sort of public and consumer customer input into what American Express or others decide that they want to do with data.

Mark MacCarthy – Georgetown University – Adjunct Professor
It's not organized. It's individual, so they'll send you a notice, and then you, as an individual, can respond to that notice. But there's no—American Express ….

Christine Bechtel – National Partnership for Women & Families – VP
There's no sort of aggregated kind of, is this a good idea? Let's get some public input. It's more, we've decided to do this, and we're letting you know.

Mark MacCarthy – Georgetown University – Adjunct Professor
Yes. American Express may run a kind of internal consumer advisory group where they bring in consumer representatives to talk about this kind of stuff, but that's not public. The only public input is through the political process. Other than that, they treat you as a consumer, and you can react individually. But your role as a citizen where you might have some public input has to go through the political process.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Let me just sort of ask a clarification. The overarching security body—I forget the name for that—only has representatives from the industry and not from consumers?

Mark MacCarthy – Georgetown University – Adjunct Professor
I'd have to check the latest membership. My memory is that the executive committee is entirely composed of by the industry. There might be people on their advisory board who are from the consumer world, but I don't think you have any decision-makers involved in that. Again, I'd have to check to be 100% sure. But I don't think there was the choice of a consumer representative to be on that board. You have people from the financial world. You have people from the merchant world, processor world, but I don't think you have consumer representatives in it.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
John Glaser?

John Glaser – Partners HealthCare System – VP & CIO
Yes. I find the tasks that we have complicated, and I don't quite have my hands around it. Maybe the rest of the committee members do, but I think there's sort of two pieces to it. One is, what do you govern? That's actually less complicated to me than the challenge of those who you want to govern, what makes them willing to be governed? I think there's probably a couple of conditions that sort of sit underneath this. I'm going to try to tease apart what those are in these respective things.

One is that me, as an individual actor, I see an upside to being governed by this, so there's something in it for me. Now maybe it's getting people to show up at my restaurant with a Visa card or maybe it's getting a narrower range of quality measures, which would make my life easier. There's probably some

belief that if I act unilaterally, I diminish my ability to get my value because I'll erode the trust fabric or there are other consequences. So operating in unison with others is very self-fulfilling to me because I leverage my value.

Probably the third—and I'm sure there are other things—is there some peril to me ignoring the governance structure if something bad happens to me. Now it could be value loss, which could be me getting kicked out of Visa. We'll just kick you out as a merchant, or we kick you out as a bank if you don't conform, and that has consequences to me here.

What I'm trying to figure out, Laura, is the consequence if I ignore the NQF consensus process and decide I think I'm, for whatever reason, going to do it differently. What are the consequences to me, if any? Now it may be, if I'm teasing apart here, because it's a voluntary standards consensus organization, my ability to interact with government just got impaired. Maybe I think that's a big deal. Maybe I don't think that's a big deal. It may be that if I'm trying to rely on a market that is centered around software that does all this stuff or exchanges this stuff, I just made it a lot more expensive for me to deal with that thing because I have to do a one-off and go off and do this.

But what are the consequences in the NQF of people who blow you off? Not that directly, but you know what I'm saying. Part of it, is there a peril element here? What is our equivalent of the peril element? I don't mean to make it sound onerous or scary, but there's got to be some consequences to ignoring the governance.

Laura Miller – National Quality Forum – Senior Vice President & COO
Clearly, NQF does not have any responsibility for oversight of utilization of measures. We are endorsing measures and then promoting public reporting, including public reporting and hospital compare and other mechanisms, and see those as the opportunity to influence the utilization of the measures. But we don't obviously have any enforcement authority. I think educating consumers about measures, educating providers about the utility of utilizing standardized measures, providing input to the selection of measures by CMS and others are of the mechanisms that are the enticements, if you will, to the utilization of the standards.

John Glaser – Partners HealthCare System – VP & CIO
I don't think that's the enforcement per se where you deny them the ability to do this, that, or the other, but there's some consequence to doing that. So maybe it's a softer consequence.

Laura Miller – National Quality Forum – Senior Vice President & COO
I would say, if I were, as a provider, interested in knowing how my work compared with others, I'm going to want to use standardized measures. I think individuals who are providing care have that incentive. I think there are incentives out there. They're just, maybe as you say, a little bit softer than the financial incentives or the compliance incentives.

Mark MacCarthy – Georgetown University – Adjunct Professor
Could I just jump in there a little bit? I think they're a little bit stronger than that. Certainly there's a requirement by CMS to report measures of physician performance now, as well as hospital performance, and those are tied into reimbursement. There's NCQA using NQF measures, and those also are tied into various other reporting that are directly tied into reimbursement. So I think it's less direct, but there are some indirect measures that are financial in character.

Christine Bechtel – National Partnership for Women & Families – VP
If I could just add, the other piece of that is beginning to see some statutory language that could require the government to certainly at least prioritize the use of NQF measures, if not actually only focus on those.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
The benediction question goes to Laura.

Laura Adams – Rhode Island Quality Institute – President & CEO
I have just two quick observations, and then one question for you, Laura. The observation is I was so struck by the ability to immunize the consumer in your industry. I think, in ours, is there ever a way that our customer, our patients can ever escape liability in the sense that a brief of your personal health information is like slitting a feather pillow in the wind. To be able to retrieve that information, there's irreparable harm in many cases that no amount of money can ever restore that. I think there's an issue for us to deal with there.

Secondly, in thinking about one of our questions before us is how do these things get started. So I want to think a little bit about the role of government as a proxy for the broad range of stakeholders when there's no obvious alternative in the sense of who gets to decide in the beginning. I think, fairly obviously, in the case there, you had major players. Those major players could come together, and no one could oppose them.

Laura, I'm interested in understanding how the NQF first governance board was established. The question of who is so critical in the initiation stage of something like this. Did the government have a strong hand in that as a proxy for stakeholders? How did that happen? Who became the first board?

Laura Miller – National Quality Forum – Senior Vice President & COO
Unfortunately, my history doesn't go back that far in terms of who specifically was on the board at that point. It's my understanding that it was a group of healthcare leaders and some government leaders who came together and identified the need and convened a public nomination process. I don't know specifically what hand government took in that process.

Mark MacCarthy – Georgetown University – Adjunct Professor
Again, I'll jump in because actually I was on the NQF board in the early days, and that board was formed based upon, there was a presidential advisory committee on quality of healthcare. They recommended the structure of the NQF as a public/private partnership. There was an exploratory committee that was then formed, and the board was composed at that point, designed to represent the major stakeholders.

Laura Adams – Rhode Island Quality Institute – President & CEO
So it was under the auspices of the government, at least quasi.

Mark MacCarthy – Georgetown University – Adjunct Professor
Yes, it was designed as a public/private partnership from the inception.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
It's time for a break, but before we do that, Mary Jo has something to say.

Mary Jo Deering – ONC – Senior Policy Advisor
Well, I will perhaps—and Mark may have to follow up in writing because I know we are out of time. But I'm actually channelling Elliott Maxwell here, who points out that perhaps a question to ask Mark is do variations in state law affect your ability to execute your governance framework?

Mark MacCarthy – Georgetown University – Adjunct Professor
The one example that I can think of is the kind of state law that I referred to earlier where, for example, Minnesota made it a matter of state law in their state to follow elements of the PCI standard. If a company didn't do that, and is then the victim of a breach, the entities who had financial loss associated with that breach could then bring a claim against that breached entity. That was under state law, and other states are looking at that. I think Texas is looking at it. California was looking at it. At the state level, that kind of fragmentation could create a difficulty if one state has one set of security standards; another state has another set of security standards. That could create a kind of difficulty.

If there is going to be a kind of uniform approach to security in this area, it probably should best be done at the national level rather than at that state level. I don't think it makes a lot of sense to prescribe specific security requirements, let's say, requirement 10.2.1 is now hereby codified. But it probably does

make some sense to put in a general obligation for all entities to keep information safe and secure, and make that a matter of federal law. If you fragment it at the state level, most of the players operate across state lines, and that could create some difficulties.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Laura and Mark, thank you so very much for not only answering some difficult questions, but also submitting written testimony, which we'll use as part of our deliberations. We have a break until 10:45.

(Break.)

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
As the keeper of the clock, I'm going to invite everyone to please come back to your seats. We have a lot of good speakers, and we want to make sure we have time for questions for all of them.

Great. We're now going to go to our second panel. For those of us who are here on the committee, we will now share our experience with those who are online because our first speaker, Jac Davies, is also here electronically. If you wondered why you couldn't see anybody sitting in that seat, it's not that they're invisible. Jac, are you there?

Jac Davies – Inland Northwest Health Services – Director
Yes, I am.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Jac Davies is director of program development, has a leadership role in the beacon community. I'm sorry, my note just didn't print. Inland Northwest Health Services beacon communities, that's the part that's missing. Our next speaker is going to be Maggie Gunter, who is the president of the New Mexico Health Information Collaborative and president and executive director at Lovelace Clinical Foundation.

We're going to have a slight switch in this panel and panel number three in that Rachel Block, who is the deputy commissioner of the Office of Health Information Technology and Transformation of the New York State Department of Health will be here from the New York eHealth Collaborative instead of on panel three. Stephen Ondra will be following up on the panel this afternoon.

So we'll start off with Jac.

Jac Davies – Inland Northwest Health Services – Director
Thank you so much for giving me the flexibility to speak to you buy phone rather than flying across the country. I do appreciate that. Again, I'm Jac Davies. I'm director of the beacon community of the Inland Northwest speaking on behalf of Inland Northwest Health Services (INHS) in Spokane, Washington.

INHS has been conducting regional health information exchange for more than a decade surveying hospitals, physician offices, clinics, laboratories, and imagine centers in Washington state and Idaho. INHS is governed by a board of directors representing the two hospital systems that first formed our organization and also representing members of our community. In addition to the formal governance structure, INHS receives guidance from multiple community-based advisory groups, including the informatics committee of the Spokane County Medical Society and a regional health information management workgroup.

Input from the board of directors and from the various advisory groups was used to develop and is used on an ongoing basis to refine contractual documents that establish the roles and responsibilities of all the organizations and individuals participating in health information exchange. If the participating organization is paying for a service such as a hospital or a physician office receiving EMR support in addition to health information exchange, the contractual documents cover the costs and scope of that service, as well as responsibilities related to the HIE. If the participating organization or individual is only accessing information through the HIE such that a physician in a rural community who is seeing the

patient, the contractual documents only cover the privacy and security requirements associated with the HIE itself.

Trust in the exchange is established through the use of the common contractural framework that I just described. I've noted this common framework covers privacy and security obligations, including the appropriate use of data. All participating organizations are aware of the contractual requirements and the knowledge that everyone must comply with the same requirements to build the trust. When an organization raises concern over a specific issue, that issue is discussed with the advisory groups and with the other members of the exchange. If necessary, all contracts are updated to reflect whatever changes were agreed upon.

We're fortunate to be serving a region that has a strong history of collaboration between residents across the board, including healthcare organizations. In healthcare, the collaboration is based in large part on the realities of meeting the needs of patients who live in rural communities across a very large area and who move between multiple providers. The regional HIE has levers to that collaborative history, as well as the existing relationships to promote effective participation. There are active regional workgroups, advisory groups, and coalitions on a variety of topics, including health information technology, medical record, medical office management, healthcare research, and chronic disease.

Rather than trying to build new HIE specific groups, we have relied on these existing relationships and collaboratives. This has helped us maintain active participation across a variety of organizations and interests. Consumers have also been engaged both as part of the existing advisory groups and through the creation of advisory groups that are on topics that have strong consumer interest such as personal health records.

We believe very strongly that HIE governance cannot be mandated from the federal level, but instead should be driven by the particular business needs and relationships within each community. The ONC can help by providing templates and other sample documents that communities can adapt to meet their needs. Ideally there will also be a minimum set of functions and policies that HIEs should comply with in order to assure interoperability and the extension of the trust framework between HIEs. However, the exact governance structure should remain within the purview of each community.

As with the other aspects of our HIE, interoperability is maintained through contractural relationships. Organizations that participate in the exchange of information agree through contracts on the mechanism that will be used, including data type, data format, and messaging systems. By complying with these requirements, interoperability is enabled and insured.

I believe there are two potential roles for ONC in this arena. As noted above, ONC can and has, through the NHIN process, establish a minimum set of functions and policies that any HIE seeking to exchange data outside of its boundaries should follow. Those functions and policies would define both the technical requirements for exchange of data between HIEs, as well as the trust framework for privacy and security to assure any participating organizations that their health information is going to be treated appropriately.

A second role for ONC or an ONC approved body is to establish a certification process to identify the HIEs that meet the desired functional and policy requirements. This wouldn't be a certification process for HIE products, but rather, a process for any HIE organization that seeks to share data with other HIEs. Focusing on the organization rather than the technical solution will help assure that the certification process captures policies and practices that are outside the realm of technology.

The current assumption is that HIEs will link to each other via the NHIN Connect gateway and, therefore, will meet the NHIN requirements. If that's the case, is a separate certification process necessary? We believe it is because at the community and regional level, we are learning there are likely to be linkages between HIEs that don't go through the NHIN Connect gateway.

Health information exchange may be a function operated by a single corporation to link multiple facilities or it may be a community or state-based organization that provides HIE services. If a corporation has

purchased an HIE product and is using it internally, does it need to comply with NHIN requirements and connect to the NHIN gateway? Absent regulation, is it possible to require businesses to use the NHIN gateway and associated policies?

A separate certification process would allow any organization using an HIE product and that seeks to share information outside of its own boundaries to quickly ascertain whether an external HIE meets some minimum level requirements around functionality, policy, and practices. The establishment of a certification process shouldn't preclude individual communities or organizations from setting higher standards around the exchange of information if they believe they have the need to do so. However, a common certification process would establish a minimum level for a trust framework that would apply to all participating HIEs.

Finally, talking a little bit about accountability, enforcement, and oversight, as with other aspects of our process for HIE, accountability, enforcement. Oversight are defined through the contractual framework with participating organizations. Each organization has the responsibility to make sure its employees are trained and are following the required policy and practices.

In addition, INHS maintains a complex security system that allows us to determine if there is inappropriate access to any health information and to identify when such access occurred and the individuals involved. We also rely on the participating organizations to monitor their employees and to rapidly notify us when employees leave or if there are any concerns regarding inappropriate use of health information. The rigor with which we enforce these policies and maintain the security framework has really strengthened the overall sense of trust held by all the organizations participating in our HIE.

Rather than establishing governance, ONC should establish a common framework for participation that would form the basis for the certification process I just described. HIEs that are seeking to share information with other HIEs would be vetted as far as the certification process with a review to assure that all of their policies and practices met the minimum requirements. Appropriateness of the exchange of information would be monitored at the participating organization and also at the HIE level using a combination of policies and technologies, as I've just described. Ideally, consumers who seek access to their own information from the HIE would have an electronic personal health record, which could receive data from the HIE in the same way that the clinical endpoints receive data. If the consumer is uncomfortable with an online personal health record, the HIE should have the process for copying data onto some device such as a CD or flash drive, provided that such devices are encrypted.

Consumer complaints should be investigated as a joint effort by the HIE and by the healthcare organizations that were part of the complaint. Resolutions to the consumer's complaint should be jointly reported back to the consumer so that the individual knows all the effective organizations have responded. Finally, the easiest and most effective discipline for bad actors is just to cut them off from the HIE. If they're not complying with policies and practices for sharing data, they shouldn't have access to that data. Given the various drivers and incentives that are developing for participation in an HIE, restrictions on access to shared data should encourage the bad actors to rapidly mend their ways.

Thank you for this opportunity. I'll be happy to take your questions after the other speakers have presented.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you so much. Maggie?

Maggie Gunter – New Mexico Health Information Collaborative – President
Thank you, Mr. Chairman and members of the governance workgroup. My name is Maggie Gunter. I am president and executive director of what we now call LCF Research, formally known as the Lovelace Clinic Foundation. We're a nonprofit organization in Albuquerque that created, manages, and operates the New Mexico Health Information Collaborative, which we called NMHIC. That's so you'll have another acronym to add to your list. We are the state's designated entity for health information exchange.

My main focus in my remarks concerning is about the governance issues we've encountered and discussed in developing and operating New Mexico's health information exchange in the following topic areas: trust in governance; privacy and security, which I have to tell you has been much, much more difficult than we thought; interoperability; and the respective roles, some of my thoughts on the respective roles of the federal government and the states.

First, as a context for my remarks, I'd like to provide you a little bit of background concerning our organization and its involvement in leading the state's HIE. I think a lot of ... that different kinds of organizations lead these initiatives, and some of them that have something to do with the kind of governance structures we have. I am a health services researcher and medical sociologist, and I always hear that running and putting together an HIE is more about the sociology than the technology. I have to tell you that being a sociologist, I think, frankly, they're both hard.

One of the things that had happened, as some of you know, Dr. David Blumenthal is also a health services researcher, and when he came to visit with us in June of this year, he commented that he found that it was interesting that a research institute was leading the state's HIE. First of all, we're a very applied health research institute. We've always been involved in innovation. So our interest in initiating the health information exchange has really stemmed from early pioneering work we'd done in the area of provider-based disease management in the early 1990's with a large, New Mexico, integrated system that some of you know, Lovelace Health System. Our recognition that even though we did some good work there and, I think, made a difference for patients, that our work would have been even more effective and sustainable if full, electronic medical records and the associated performance indicators and data had been available then. If there had been the capacity to have a patient's electronic health data follow them across the community and across healthcare organizations.

Like many of you, a number of the systems around the country, we started with an agency for healthcare research and quality award in 2004. From a governance perspective, I think that AHRQ did a very good thing in that they required that anybody putting in a proposal to start an HIE would have to have 100% community match. That really started our governance process of engaging the community. I think that was very wise of them to require that because that meant you had to go out and get some initial interest and initial consumer engagement because you needed to have people that wanted to work with you and were willing to provide some community funds.

We've done a number of things over the years, including we were part of the first nine of the folks that were part of the—we don't say now, do we—the Nationwide Health Information Network, trial implementation project, and that really helped us get our governance going even more distinctly, get our HIT infrastructure going. We were then designated as the state's designated entity for ARRA purposes in 2009, and have been fortunate enough to be both operating the state HIE with ONC funds, but we also are operating the regional extension center. That means that under one governance structure, we have both of those major projects to improve HIT in our state, but we also have one of the Social Security Administration projects to expedite the current cumbersome and paper-based process to apply for SSA disability. One of the things from a governance structure, it's nice to have a management and a governance that is sort of compatible over a number of our HIT initiatives.

Just to let you know, we have an e-reporting initiative with the New Mexico Department of Health that is now live and channels lab results on notifiable conditions, as well as emergency department utilization, data from health systems from the department of health using the HIE, our first real paying customer other than, bless you, ONC, the grants from the federal government. We now have a very well populated, master person index. We only have about two million people in New Mexico. We now have 1.3 million unique patients in our master person index, so making some progress.

For us, it is not going to be as we move closely very soon toward full clinical use, it's so critical that we have all of the major players, so that it's actually useful and that there would be good adoption by clinical users. So the good news is that the university of New Mexico Health Sciences Center that has kept saying that they want to play is expected to join us as data supplier and participant by the end of 2010, and that's a real milestone for us because it will mean that it is a much more useful kind of thing if the full

range of data is available to physicians that want to use the HIE. We're moving to operational clinical use at the end of 2010. We know that and are working on it hard means a number of new governance issues have to be resolved in terms of standard user policies for joining the exchange and using the exchange as a clinical user, and we'll talk a little bit more about that.

When we think about governance at the local or state level, one of the things I know most of us know that while there are some guidelines for governance, and that is, I would say, things of how important it is to have your particular stakeholders appropriately represented, and I can't always tell you what those are. But it better include things like, folks like consumers and employers and health delivery systems. We know some of that. But again, it will really depend to some extent on the particular stakeholders in your state, its particular demographic characteristics and culture, and its unique healthcare delivery structure and politics. One size does not fit all, but I think that every HIE will need to examine its own community landscape and make careful decisions to be inclusive of the major stakeholders in their region and state.

One of the things we struggle with in governance, there are people that look at our new, enormous board, and we do that on purpose to have community buy in. It has about 35 to 40 members. But we also have key committees that allow us to be a little nimble because the issue is how do you balance the benefits of inclusiveness with the need to have a governance structure that's sufficiently nimble and flexible that it can respond reasonably quickly to changing needs and requirements. Some of you noticed that run these how important it is to be able to be nimble because things are changing all the time. So management, the distinction between what management does and what governance does when I think of governance, I mean often the board and all of those governance structures is often an issue that we need to work through further all the time.

Our governance structure has evolved, along with our health information exchange network from an advisory group. In the early years, it was really a project-oriented group that I think people thought sometimes was just a project. We never saw it that way. We certainly had great hopes that this would be a major initiative that would have legs and would make a real difference for healthcare. Today, we have a statewide board of directors that now has true oversight over all of Lovelace Clinic Foundation, now known as LCF Research, when I can remember, as a whole, including specific committees that monitor its HIT and its research functions.

I think I'm just going to move through some of this. One of the comments that I will make is that we have always had a public/private partnership, but as we have put together, went from an NMHIC steering committee that was advisory to an LCF board that really manages us, and that was a distinct difference for us. We knew that meant that there was real governance, that there was real structure that we needed to respond to as a management team. We also added, because it was very important, the New Mexico Medical Assistance, The Medicaid division, and representatives of a number of rural hospitals and medical groups. I wanted it to be a true, and we did, statewide initiative.

I grew up in a rural area in Grand Junction, Colorado. I remember how we felt about that Denver ran everything, and I really think it's critical. See how our personal experiences shape how we think. I sense that they appreciate that, and they have been very active on our governance committee, some of the rural areas, and I think they've been very important. We're a rural state. We need to make sure it's not just about Albuquerque.

The whole issue of trust is interesting because, notice our name. From the very first we knew that our name was Lovelace Clinic Foundation, that we were associated. We were not likely to be perceived as neutral. All the guidelines, we didn't really fit those, did we? We were associated in a research way with one of the large, integrated systems in the community. So we knew from our proposal stage with AHRQ, that we needed to be very careful to understand that neutrality in leadership and governance was very important, was such a new and innovative enterprise. So from the very first we said, including in the proposal, that we would incubate the program, but we would in fact establish a separate community-based board, help them achieve 501-C3 status.

A lot of people thought in our own organization that we were crazy. But one of the things that we have been committed to from the first is that if it's about us, it will never work. It has to be a collaborative speaking of trust. So what we did, we supported the creation of something called the Rio Grand. You've got admit that RHIO grant is just one of the best names, so that's been one of the saddest things about giving that up, as eventually happened. It was established along with a new board of directors. I was on it, but only one of numerous people. As all of this progressed, LCF continued in NMHIC to develop to get additional grants and, over time, it was interesting to watch the trust develop. I think one of our strengths is that we have an honestly collaborative group that leads our organization. If they weren't, I think honestly they weren't comfortable.

We, over time, found that there was in fact an effort as trust developed in management where they agreed without our really pushing for this at all to say "You all have been the folks that have developed this. Why don't we merge our initiative into yours so that we will just have a single initiative, and we can move forward?" One of the other things that we have done in recent times that I think is important is that there needs to be an important sense in the community that this is not per se LCF, but this is the community's public utility. We have established a sustainability taskforce, not just to see if we can get money, but so that the community can really say these are the kinds of services that we will find out of all the things you might do the most useful, and that some of us would actually pay for because we know that the federal government's work can only be the seed money. We need eventually to be on a much more sustainable basis, and that this kind of approach will build ownership in the community.

One note about consumer involvement: I still think we're not there yet, and I was thinking of John Lumpkin in his work with Robert Wood Johnson. We're working with the Robert Wood Johnson funded aligning forces for quality initiative, which has created a very strong consumer engagement workgroup. We're trying to work with them to say how do we do a better job about engaging consumers, especially about the public concerning the benefits of the HIE, their privacy and security protections, which are in place, and their right to opt out and how to do so.

We know that we will need new provisions in governance, as we move into live production with clinical users. How do we make sure that users do not abuse the policies of privacy and security and appropriate use that are being established at present? What sanctions should there be? Those are issues we're looking at.

I'm going to go ahead and move down. There are lots of issues in privacy and security that we have dealt with, along with a lot of the rest of you. There are key issues. We've helped pass new state legislation that will authorize electronic medical records as legal documents and to address the privacy and security issues relating to the operation and the use of HIN. I will tell you that that passage of that legislation was a lot of input really was a key factor in reducing legal concerns of data suppliers.

We wanted to not miss talking a bit about when we think about what kinds of things could our state government structure really benefit from the federal government, because I know you're all thinking about those kinds of issues. One of the things, in addition to issues of, of course, interoperability, standards, and so on is many times guidelines, tools, incentives are very powerful and helpful to still allowing flexibility at the state level.

Let me just mention, as I close here, several different areas: One is effective methods of mapping and translating. The lagging standards typically used we're finding in many of our local health systems, so they're consistent with approved federal interoperability standards.

The other is models for uniform patient consent and/or a process of harmonizing the conflicting levels of consent required under different state laws. I don't know about laws in your states, but ours are some of the more rigorous and restrictive than HIPAA. That means that all the work we've done with DURSA is sometimes difficult because we sign DURSA, but we're not quite sure how we would exchange information when we require written consent and other states do not. So those are the—even for treatment we do.

The other thing is it's the messages that we convey to all kinds of stakeholders about HIE benefits, privacy and security issues. The more we could have help from the federal level with those kinds of messages that often are too expensive for us to do at the local level that can be tailored for different stakeholders and audiences, but then adapted to the specific needs of the various states and locals would be an enormous benefit, I think, as one very supportive health plan CEO said a number of years ago that he thought the idea of sharing data across organizations was great. But was there a Petri dish somewhere that could demonstrate its value in a real world setting?

Related to that, whatever we can do at both the state and the national level to create careful and creative evaluations of our existing processes and outcomes is key to continuous improvement and to stakeholder engagement and sustainability. I have to say that in my time in healthcare, I have long been concerned that there often seems to be funding to establish new health programs, but very insufficient funding for evaluation to assure that they are effective and the guide needed revisions, so if possible, a national effort. I know there's a lot of informal work done to identify and study lead prototypes of health information exchanges, which have established effective processes and governances, but if we could do a more specific area in that, it would be wonderful.

And the last is something that was brought up, I believe, by Christine Bechtel, and that is about financial. What are the methods that could be developed to facilitate the use of HIE data for purposes beyond treatment while protecting privacy. Secondary uses are going to be so important to healthcare reform, and we have to figure out the best ways to do those things. Thank you very much.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Rachel?

Rachel Block – New York eHealth Collaborative – Executive Director
Thank you for the opportunity to speak to you today about governance. In New York State, we've been advancing statewide health information technology strategies since 2006 and governance is really a very central consideration in terms of how we've approached that effort. We have committed approximately $400 million of state and federal funds through the Heal New York program to advance broader adoption and use of health information technology in order to really spur the transformation of our healthcare system. And so we literally have a direct stake in making sure that those efforts are successful and that we have strong policy and standards associated with it.

We also have been involved in a collaborative, statewide model for governance since the beginning, and we often refer to this as the secret sauce that has really helped to keep everybody together in terms of supporting both local efforts to implement health IT effectively and engage local stakeholders, but also to make sure that they're bound together by a common technical and policy infrastructure. We also have utilized a public/private partnership model, which exists at both the state and local level. The New York State Health Department, which provides funding, as I mentioned, as well as strategic policy direction.

The New York eHealth Collaborative, which is an independent, nonprofit corporation, established expressly for the purpose of convening stakeholders and managing a consensus process of the development of policies and standards to govern participation in and the use of health information exchange. NICE is under contract from the state health department to operate what we call the statewide collaboration process. That's the mechanism through which we develop those policies. And those policies then in turn govern all of the activities of the grantees who are receiving state funds. Another component is our policy and operations council, which is comprised of all the projects receiving state funds, so they literally have a vote, and they are required to participate in the process of developing consensus on those standards.

Finally, regional health information organizations, which themselves often are public/private partnerships involving, in particular, local health departments in many instances, which establish community level governance that bind the participants to following those statewide policies, but also determine how information will be shared within the community to improve patient care and population health based on

specific resources and priorities established at the local level. Now just as a sidebar comment, it turns out that this regional governance structure particularly comes in handy as we're navigating very interesting and challenging issues of how health plans and providers are actually going to engage in a constructive way in terms of agreeing on how health information will be used for the variety of purposes that we anticipate health IT supporting.

Our governance structure is dedicated to developing and operating what we call the Statewide Health Information Network of New York, or SHINNY. SHINNY is based on a federated network. It is a network of networks governed by common protocols, standards, and policies. So, in that respect, at a very high level, it has some similarities to the Nationwide Health Information Network. In fact, we participated in the trial implementation and some subsequent efforts for NHIN.

RHIOs are responsible for enabling interoperability among community stakeholders to make sure that they are both organizationally and technically connected to each other in a coordinated way. They provide services to advance interoperability, but they are not themselves vendors. They are community-based governance bodies who contract for the necessary technical services based on the input that they've gotten from their local stakeholders in terms of what's needed to connect that community.

They must adhere under our contracts with them to requirements in several different domains: organizational, which includes their corporate structure or composition and certain requirements about how they maintain data exchange agreements; clinical, including clinical participation in both governance and implementation areas; technical services, which I mentioned; financial requirements, which address their need to maintain financial systems and have appropriate business plans for their activities. There are significant matching funding requirements for all of our grants, so the stakeholders are not only participating from an information exchange point of view, but they're actually participating financially as well. Finally, privacy and security, of course, we have a statewide consent policy, which all of the RHIOs have implemented and many providers are now actively engaged in implementing.

The operation of the statewide collaboration process and the issues that we've addressed through the statewide policy guidance really are specifically designed to establish trust and maximize the value of interoperable health IT. While many of these policies and standards have specific applicability to certain policy initiatives, which were important to the state under these grant funded programs, many were designed to insure broader adoption and use of health IT independent of those grant dollars.

With respect to accountability, oversight, and enforcement, obviously as I've indicated, we have a coordinated approach to try to insure accountability. We primarily use contracts at this point to insure the use of those policies and standards by the RHIOs. The RHIOs in turn are expected to incorporate the need to follow these statewide policy guidance into any contracts that they have with vendors. We also have now extended the use of this vendor contractor requirement to our certificate of need process thereby further insuring that any health IT implementation advancing in New York State through hospitals and community health centers subject to those requirements will follow state policies for interoperability and will be able to be technically interoperable with the statewide health information network.

But those contracts eventually will end, as our grant dollars and funded programs will come to an end. We'll have a couple of more years where that will remain an effective strategy. But we also recognize that we needed to move towards a more formalized regulatory model for health information exchange, and that will really establish the requirements for HIE that will transcend those limited grant funding opportunities.

This past year, we got legislative authority from the legislature to granting the commissioner broad authority to regulate health information exchange activities in New York, including such measures as may be necessary to insure compliance with federal rules and policies. This way we'll be able to make sure that we have consistent implementation of all federal rules and policies while also meeting state needs, including the further advancement of our privacy and security activities.

We also have provided funded and established some additional contract deliverables for NICE to develop to develop recommendations to us with regard to RHIO or HIE accreditation, which may well be the model that we would choose to follow in the future. And I would mention, finally, that an important new tool in our toolbox is the active engagement of our Medicaid agency and the Medicaid program, which obviously has a specific role in terms of the implementation of the meaningful use incentive payments, but has also taken additional steps to advance e-prescribing, medical home, and other things. And so additional requirements can be now really reinforced through Medicaid requirements on Medicaid participating providers.

In terms of some considerations for the HIT Policy Committee and the Office of the National Coordinator moving forward, I think, from a state perspective, the future governance model for HIE needs to consider the multiple regulatory and policy roles that states currently play and which will need to be aligned from both an organizational and policy perspective. Many state programs of which Medicaid and public health are obviously notable, are subject to a variety of different federal and state requirements, and many states, as Maggie noted, have specific laws governing privacy and confidentiality of health information. In the absence of a sweeping new federal regulatory framework that would preempt state law in those areas, it would make sense to leverage the existing state level regulatory capabilities and requirements and include some form of federal/state partnership in terms of the future governing model for health information exchange.

In addition, the policy committee recently adopted recommendations relating to consumer enrollment in health programs, and hoping to advance more standardization and simplification of those efforts. States operate a variety of disparate systems for provider enrollment and accountability, so I would offer that the policy committee might consider convening a separate workgroup for the purpose of developing national standards for provider enrollment and accountability systems and processes that would both streamline the process for providers to enroll or be certified for these purposes and provide a mechanism to implement any applicable standards more broadly. Finally, it might be desirable to have a national accreditation program for qualified health information exchange entities so long as the development of standards and the implementation of such a program would be conducted in some manner through a multi-stakeholder governance model. Thank you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you. Christine, I think you were first.

Christine Bechtel – National Partnership for Women & Families – VP
I have generally the same question for all three of you, but I'll adapt it. First, for Jac, on the phone, you've talked about consumers on an advisory board that you have. Are they also on your board of directors?

Jac Davies – Inland Northwest Health Services – Director
Yes. We have consumer representation on the board of directors as well.

Christine Bechtel – National Partnership for Women & Families – VP
Is it one consumer representative or more?

Jac Davies – Inland Northwest Health Services – Director
It's one because it's a small board of directors.

Christine Bechtel – National Partnership for Women & Families – VP
Maggie, the same question, although you talked about a special—I forget what you called it—but a special board committee, I guess, that oversees the HIE. Do you have consumer representation on that?

Maggie Gunter – New Mexico Health Information Collaborative – President
We have assured that, and I'm being honest, been concerned about really engaging consumers in a meaningful way and what is a consumer, and so we've worked on that issue. Just quickly, we've had consumers from the very first in that it was a non-health consumer leader in the community whose idea it

really was to say why can't, when I go to my physician, why can't he or she get information from wherever I've been seen? That particular consumer was a major leader in this initiative.

What we do now is have a formal requirement that we have consumer representative on both our HIT committee and our overall board. What I am concerned about at this point is to make sure what is our best approach with insight from those folks about really talking to the community in an effective way to those consumers and explaining, as we really move into full clinical use, how do we really do that effectively so that they have the opportunity to opt out. I think those are the things that I'm most concerned right now with making sure that we leverage our consumers that we're working with that we further work with other governance committees like the quality initiative that is aligning forces for quality. They have a major consumer workgroup that we are working with now to say how do we make sure we align these initiatives that are quality in HIT. Remember, we're a fairly rural state, and we don't want to duplicate efforts all the time, so we're working with those consumers as well to further engage consumers.

Christine Bechtel – National Partnership for Women & Families – VP
Let me draw a quick distinction just to make sure that my question is clear. There are two ways that I think at least two ways that I think governing bodies should "engage consumers". One is the area you're focused on, which is really more education. This is what we're doing, and this is how it's going to impact you, and we really hope you support that. But much prior to that, and by far in my opinion much more important is the opportunity for consumers not to sit on an advisory board that is out in the hinterlands that has no decision-making authority, but really to have a meaningful voice and ability to shape the decisions that are made.

When I was highlighting NQF earlier, they have multiple consumer representation. The policy committee has three consumer representatives statutorily. When I read your testimony, and I picked up on the privacy and security challenges you're facing, your desire to clearly use secondary data as part of your business model and sustainability, that raises a lot of alarm bells for consumers, and so I just want to make sure that you've got not just one or two, but robust consumer input into how you handle sensitive health information, how you're going to use secondary data. That's why I'm asking about the role in that committee.

Maggie Gunter – New Mexico Health Information Collaborative – President
There's an irony to this. I, as a researcher, felt it was terribly important that we not concentrate on secondary use. We, in fact, from the very first concentrated on treatment only because we thought that that would be, and we talked to the community, and talked to various people in the community about what they were comfortable with. We engaged consumers from the very first in that standpoint, said this is not anything about our needs, even though there were people at the state level that were very excited to think we've got all these holes in our understanding of information. I said that sounds fine, but we need to start where the community is, and that is to use it for treatment only.

Christine Bechtel – National Partnership for Women & Families – VP
I'm sorry because we're going to run out of time, and I want to ask Rachel ….

Maggie Gunter – New Mexico Health Information Collaborative – President
Just quickly, we do in fact have, and have from the first, consumers on both when there was only an advisory committee. They were key members of that advisory committee. They're now a key member of our governing board. They're on the HIT governing board. We'll make sure that that is the case, and has been throughout our initiative. I just think it needs to be broader.

Christine Bechtel – National Partnership for Women & Families – VP
Rachel, you've gone through actually a whole consensus process statewide, and I know you've had really robust consumer representation. Do you want to talk about that?

Rachel Block – New York eHealth Collaborative – Executive Director
We tried to have a very comprehensive approach, again, at both the state and local level, so NICE has consumer representatives on its board. It is a self-governing body, so they decided to do that. It wasn't

our decision, but it was a good decision for them. As part of that statewide collaboration process, they have managed a consumer advisory council that is advisory, but has actually voted on all of the policies that have gone through that process, so they actually did have a decision-making role in that respect, and it's provided a great forum for them to become much better informed about the key policy issues that we're navigating through. At the local level, the RHIOs are also required to have consumer representation in their board and all of their activities, just as they are expected to have direct clinical involvement in their boards and all of their activities.

I'll just mention as one example of, I think, a really interesting project out in western New York. Western New York Healthy Link is the RHIO. They have spearheaded many of these collaborative efforts locally, but the P2 collaborative is the awardee of the Robert Wood Johnson Aligning Forces for Quality grant out in that community. Western New York Healthy Link also just was awarded a beacon community grant, so all these things are starting to converge in that community. The specific focus for the P2 collaborative was to do the crosswalk in terms of how quality information will be communicated to and used by consumers and how quality information will be communicated to and used by providers and to really approach that in a very sort of integrated way with consumers, health plans, and providers all integrally involved in the process of providing input into and helping to decide how that will actually work most effectively. It's just one example of a particular community level effort that's really trying to pull all the pieces together, not only focused on policy, but really on how people will really most be able to benefit from the use of this information as well.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Maggie, just to be clear, you have no governance set up for research now. You've made a point of focusing away from research at this point?

Maggie Gunter – New Mexico Health Information Collaborative – President
Yes. We have a network subscription agreement for those. It specifies that it will only be without explicit patient consent. Otherwise the data from the HIE will be only used for purposes of treatment and only if there were other explicit written consent by patients for other uses. So that's the way we see it, and that's kind of the governing agreement that people are assigning and having input to, as they join the ….

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Rachel, you talked about accrediting HIEs, and you were pretty specific, but I just want to double-check. By accrediting, you mean accredit the organization, as it operates, rather than certifying the software that it operates on. Okay. Given that New York State is a mini NHIN or the term that was formally known as NHIN.

Rachel Block – New York eHealth Collaborative – Executive Director
We like to think of NHIN as a big SHINNY.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Right. Yes. Maybe that would be the new name, the big SHINNY. How's it going? How many HIEs are up and operating? What is the depth of their penetration or their communities and so forth?

Rachel Block – New York eHealth Collaborative – Executive Director
I'll try to answer that briefly. We're just approaching the end of the grant period in which many of these RHIOs were expected to become fully operational and to have the capability to serve a significant number of stakeholders in their community. As you might expect, there is some variability in terms of how far they've gotten. Some are operational today and have very robust health information exchange activities underway, also have very robust numbers in terms of the patient consent, which are necessary. We also have separated out consent for treatment, consent for health plan use of information, and consent for research as three separate consents that eventually will be implemented.

Right now, we have a number of communities where that health information exchange is fully operational. We have other communities where we expect it to be operational by the end of the contract period, which will be early next year. There are a variety of reasons that some are a little bit further ahead. Some had earlier seed funding from their stakeholders. They had a little earlier start in terms of what they were doing. Some of these communities, we have more robust EHR adoption, and there is some relationship between having it being able to support robust health information exchange and having a broad EHR adoption in the community.

There's a much stronger value proposition for the physicians and hospitals who have implemented more comprehensive systems to participate, and they have more information to share. In those communities, we see much more active participation by the providers and the stakeholders and, as a result, there's more data flowing. We do have some variability in terms of the types of data that are being exchanged, again remembering that there's a significant bottom up component to this whole process. But whatever data is being exchanged is based on national standards that we've essentially instantiated into all of our requirements.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I wrote down some others and others. Any chance of putting some numbers next to those?

Rachel Block – New York eHealth Collaborative – Executive Director
We do have numbers. Actually, we did an update for the NICE board yesterday based on our RHIO dashboard, and I'd be happy to share that.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Michael?

Michael Matthews – MedVirginia – CEO
I have a question for each of the panelists. Thank you very much for your testimony. I'll start with you, Rachel. I was intrigued by the intersection of the state regulatory … relative to HIE and governance. Can you talk about that intersection a little bit more, which informs the other and who the drivers are in that process?

Rachel Block – New York eHealth Collaborative – Executive Director
It's a really interesting question because, as I mentioned, up until now, our primary authority has been through the contracts that we have that are then tied to access to funding, and so we establish requirements in order to access the funding. While NICE is an independent, nonprofit corporation, most of their funding has come from either the state or from the federal government through their participation in NHIN. Most recently, of course, through the state HIE program and also our regional extension center. They're primarily operating with both federal and state dollars at this time.

I think that one of the purposes of the regulations, which we will be working on going forward, will be to further define the state level governance structure and what the relationship between the state health department and NICE will be, as well as to further define what we see as the evolution of our local HIE governance infrastructure and where that's going to go. As I mentioned, our instinct at this point would be to utilize something more like an accreditation model than a direct regulatory approach for reasons I could go into if you wanted to go down that road.

I think that one of the things that we're looking at right now is how do we configure the core statewide services that we particularly want to support using our state HIE grant dollars in which the Office of the National Coordinator is certainly encouraging states to move in that direction to support broader interoperability. It helps to address Wes' question in terms of what are some of the inconsistencies now in terms of both services and data exchange that are going on at the local level. Core services offered through some mechanism on a statewide basis makes a lot of sense. We're envisioning that NICE will somehow operate that service structure.

We're talking about this as though it was a public utility model, and so we're kind of thinking a little bit through of what would be the implications of a public utility model? How would we flush that out as it relates to health information exchange? Again, these are all issues, which we'll be addressing in our regulatory efforts moving forward. We're also looking at Minnesota's efforts, which you'll be hearing some more about later.

Michael Matthews – MedVirginia – CEO
Maggie, for you, with having three distinct … in your organization with the research and with the REC and with the HIE, can you talk a little bit about the implications of that for the HIE governance specifically? Does that help? Does it distract you somewhat from being so singularly focused on the issues that we're talking about today from an HIE governance, privacy security standpoint, and so forth?

Maggie Gunter – New Mexico Health Information Collaborative – President
Yes. One of the things that is important is the whole issue of bringing together, as you had said, Rachel. If you don't have full electronic medical records in your rural and your urban areas, ultimately you're not going to have nearly as useful health information exchange. One of the things that we had actually done working with the state HIT coordinator in the state department of health and with our governance structure, and he's been an important piece of the governance structure. He is chair of our HIT committee. We wanted to think how do we coordinate, and he wanted to see how do we coordinate what we're doing in the state HIE with what was going to happen with this new regional extension center.

Our state's QIO had some interest in this area. They'd done good work, as many of them have in the area of their docket program in working with rural areas to implement EHRs. So together, I think they were not quite ready. These are daunting things to do in a rural state, 1,000 primary care physicians, and get them to meaningful use in what now looks more like 18 months, and they did want to work with us. So finally the state HIT coordinator said, Maggie, would you be willing to take the lead? Then we have very much a three-part coalition with the QIO led by us.

The QIO is for the regional extension center, and our New Mexico Primary Care Association. All of these people have been active in governance, very active. The Primary Care Association is the federally qualified health centers. That made for a good group to lead that effort, and that all of them are represented on our formal governance structure as well. I think that's helped us to really further bring the groups together.

One of the things we need to do in our state is to make sure that we are not duplicating efforts, so we even involved telehealth and those initiatives as well because we think it's so important, and how can we integrate those efforts? That's what we're trying to do. In our governance structure we, on purpose, have those folks involved. I think, from a governance standpoint, that keeps everybody much more engaged in what elements are consistent with what the regional extension centers are doing and what the state HIE is doing, so that's helped us.

Jac Davies – Inland Northwest Health Services – Director
I would just like weigh in with an observation that really is, I think, a driver behind why our model is very different from many of the other HIEs in the country. Our HIE was started without any federal or state funding, without any seed funding from anyone other than the organizations that had a business need to share health information. When I say business need, I mean to share it for clinical purposes to move away from paper-based data exchange. That was really the primary driver. All of the investments were made by the participating organization. It's only been very recently that we've begun receiving federal money for projects like the beacon project. I think that history has had an influence on our governance structure because we are very understanding of what the needs are of the organizations that are using the system and because they're the ones paying for it.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Laura?

Laura Adams – Rhode Island Quality Institute – President & CEO

I think that in all the conversations that we've been having in the month leading up to this, I hear many, many, many references to public/private partnership, and while I wouldn't exactly say that the Visa system is a public/private partnership, what we did hear was that there was public involvement in that very, very privately formed group that they have and the work that they're doing. They still rely on some form of a public/private partnership, if you will, for regulation.

Now I'm very much like Michael, interested in this interplay of the public/private partnership. Thinking a little, Rachel, I'd just like to ask you. You mentioned in the certificate of need process that you're requiring entities to be technically interoperable. I'm beginning to hear rumblings across the country from consumers saying I'd like to see a new consent process happen. When an organization decides not to connect and not to share my data, I think they should ask me for my permission to hoard my data. I will speak in the terms that the consumers have used.

I'm thinking a little bit about, does it stop in your mind with being technically interoperable, or at some point in time do you see the government in New York, the state government in New York as guardians of the population, the public health who eventually compel that type of thing? Is that ever in the cards in terms of where you see that going in terms of the ability for consumers, or do they vote with their feet? They go to another health system that's maybe participating when one isn't.

Rachel Block – New York eHealth Collaborative – Executive Director
We haven't gotten there quite yet. There is an additional requirement, which I didn't mention, however, which is that in addition to following the policies and standards for interoperability, the hospital or community health center has to participate in the RHIO governance structure as well, which then governs the availability and participation in HIE in that community. So that was designed to make sure that they were in fact connected to whatever was going on at the community level. How they go about doing that, we leave up to the RHIO and the entity to determine based on how that particular RHIO is governed and operates.

At this point, we've really kind of pushed those decisions down to the local level. I think that we recognize the value of really having value based decisions driving a lot of the considerations in terms of participation, and that at this point it might be a tiny bit premature to mandate provider participation to the extent that, as I mentioned to Wes, the actual capabilities and availability of information through health information exchange is still a bit uneven. I think, at the point that we have more robust and more consistent capabilities available, then I think that that would be a time perhaps for that particular policy discussion. In the meantime, we are encouraging participation in our public health, health information exchange, as well. Actually, we think this is a strong value proposition for the providers who currently have to maintain numerous different systems in order to report public health information through the various silos of public health programs that exist at the state level.

Again, I think that this is an incentive to participate, to streamline their efforts, but also it will generate significantly more and hopefully better quality information to the state for public health purposes. I think, at this point, we really see RHIOs as governing how health information exchange operates in the availability of information at the local level, and we also see mainly focusing on incentives as a means of driving further use of the system. Hopefully, as those capabilities become more robust, perhaps at that point we won't need to be discussing mandates because we'll have … the tipping point. Everybody will be in, and everybody will be happy.

Laura Adams – Rhode Island Quality Institute – President & CEO
I think that's going to become increasingly important from the unintended consequences of accountable care organizations as we start to sort of form our accountable care organizations, and I think there may be some thoughts that there is some competitive advantage to collecting up the data. I think that won't play out, to be honest, but especially as your three-year contracts, your funding contracts begin to expire, that compulsion. There's got to be something else beyond that.

Just one more question for you, Maggie, very briefly. You mentioned that you manage a lot of these contracts. Does the state worry about you eventually deciding that you're going to change what you do

with your contracts in terms of secondary use of the data? Is there some oversight by the New Mexico state government that says eventually we think we may need to regulate this entity at some point? I'm wondering about what they're thinking relative to you have significant amount of free rein at the moment.

Maggie Gunter – New Mexico Health Information Collaborative – President
We have spent at least two or three years working closely with state legislators to get them more educated. Now that the state department of health and the state medical assistance division are very much close partners with ours, so it is an interesting thing. It is the issue of what—we have this strong public/private partnership, but sometimes you wonder, and I'm being honest here, that as about 37 of our governors, including ours, are being replaced this year, and so what we don't have, I think, other than we do have the 2009 Electronic Medical Records Act that does specify a number of things, and we have been designated as the provider. But I think the issue of what the state controls and what NMHIC controls is not fully worked out. As I've been listening to your discussion, I think that's something we're going to have to deal with a little more explicitly, so there's a comfort level. So when there's a change in administration, that you really have some solid—better hurry, hadn't we—some solid basis for going forward in terms of the state governance versus, frankly, LCF and NMHIC governance.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
John Glaser?

John Glaser – Partners HealthCare System – VP & CIO
You guys have got some great ideas for what the national governance perhaps ought to do or not do in the context where there is a viable regional or viable state initiative. Now we could wind the clock forward a couple years and find really uneven state performance. Some have not stepped up the plate, or regions where nothing is happening and unlikely to happen, or even regions where something is happening, but some provider says, I don't need you guys. I'm going to go do it alone.

Which in those situations, and Lord knows whether we'll have a lot or a little, but we're going to have some. What do you guys think that the sort of national governance ought to be when there's, in effect, no other governance at all other than what might exist between a provider, let's say, and their exchange vendor, for example. What should happen in those situations?

Maggie Gunter – New Mexico Health Information Collaborative – President
We're so anxious to answer that question, obviously, because it's so easy.

Rachel Block – New York eHealth Collaborative – Executive Director
I think there are a couple of different ways to think about that, John. One would be is there a need to further expand Medicare and Medicaid policies, as it relates to participation in and use of these capabilities. It's a slightly different way of getting at Laura's question as well. I think that it's ultimately our goal here is not simply to implement technology, but really to advance transformation of the healthcare system in a way that operates in the pubic interest.

It seems to me that one strategy to address your question would be to further leverage Medicare and Medicaid policies potentially. But even that would not necessarily address the entire spectrum because we know there are some providers that choose not to participate in those two programs. But it would result in, and we also know that Medicare, when Medicare adopts standards, you get pretty rapid and broad diffusion of those standards, and the NQF story that we heard earlier, I think, is a pretty effective example of how CMS and NQF entered into somewhat of a public/private partnership in terms of addressing some of those issues.

I think that we really should explore more closely the role of Medicare and Medicaid policy and consider very carefully what is it specifically that might be necessary above and beyond that in terms of the operation of what we might think of in the future as the Nationwide Health Information Network. Again, I'm a little bit concerned that if we don't keep our eye on the ball in terms of the alignment of policies across many different policy areas that we will not actually advance the kind of standardization that we need in order to fulfill interoperability.

Maggie Gunter – New Mexico Health Information Collaborative – President
I think that there's a lot of truth in what Rachel is saying in terms of the leadership from a number of folks, but certainly Medicare and Medicaid. I think the leadership, even in the issue of even though it's been controversial for some state HIEs of NHIN Connect, I think, is another piece in that initiative is what do we do for places for where there's simply are not viable health information exchanges, and that's another piece of how do we make those capabilities through the Internet available to folks.

I do think one of the discussions that had come up is that even though CMS is doing a great deal, frankly, in terms of meaningful use incentives, there have been some that have questioned why are you not helping fund the initiatives themselves, and that may be another thing. It is so centrally in their interest to have not just electronic health records, but to make sure that those records are in fact achieve care coordination, and that's another issue that some of us have discussed over time is the role of Medicare and Medicaid in funding those initiatives. So I think that's another piece that we need to pursue at the federal level.

Jac Davies – Inland Northwest Health Services – Director
I would also see a role for what Rachel described as an accreditation process or certification process. As I mentioned, I'm intrigued by their certificate of need approach in New York to make the involvement with the local HIE a requirement. There may be other state-based regulatory approaches as well if there were a requirement to have HIE functions and organizations certified or accredited and then a requirement to use those by all healthcare organizations.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We're pushing up to lunch, so John, you have the last question.

John Mattison – Kaiser Permanente – Chief Medical Information Officer
Very quick question for Jac Davies: In your testimony, you mentioned that the model that you would propose would be mostly local, essentially exclusively local governance through the existing entities. My question to you is, if there's an issue involving compliance between two different regional entities, how would you recommend resolving that with the governance model that you proposed?

Jac Davies – Inland Northwest Health Services – Director
That's a very good point. That's where there would be ideally some common requirements across all community and regional entities, and those common requirements would include some kind of a resolution process for dealing with the kinds of situations you described.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I'd like to thank the panelists. I'm going to sort of ask you if you could do a little bit of homework. My question, which I was going to ask, but we don't have time for you to answer is, do you share data with each other? If not, what are the top five things that are barriers to you sharing that data?

Maggie Gunter – New Mexico Health Information Collaborative – President
You mean states and HIEs?

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Well, we have three of you, one virtually. Do you share data with each other? If not, why not? With that, if we could just ask you to e-mail that answer, give it a little bit of thought, then we thank you very much for being here.

We're going to break until 12:45 and … if there are any advice about getting lunch in a reasonably short period of time.

Judy Sparrow – Office of the National Coordinator – Executive Director
I think there's opportunity in the hotel itself, and also down on Connecticut Avenue, a short walk down the block.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Feel free to bring your lunch back since it may be a little bit of a walk, and we can start, even though we may not be finished eating. Thank you.

Jac Davies – Inland Northwest Health Services – Director
Thank you.

(Lunch Break)

Judy Sparrow – Office of the National Coordinator – Executive Director
If you would please take your seats, I believe we're ready to begin. Welcome back, everybody, and let me turn the mike over Dr. Lumpkin.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Good afternoon. We're now going to move on to our third panel. This is, again, Governance Experience of Implementers of Health Information Exchange. Our first presenter will be Stephen Ondra from the Department of Veterans Affairs. He's trained in spine surgery and reconstruction in both neurosurgery and orthopedic specialties. He spent some time in one of my favorite places, which is Northwestern University, where I went to medical school back in the day.

Our second speaker is from Surescripts. He's Paul Uhrig, General Counsel and Executive Vice-President. He oversees all of the legal matters, corporate development and federal legislative affairs for Surescripts. Tom Wagner, Chief Technology Officer for MedPlus/Quest, previously MedPlus Vice-President for Strategic Planning.

We'll start off with Stephen Ondra.

Stephen Ondra – NeHC – Senior Policy Advisor
Well, thank you, John. For the record, I want to point out that Northwestern is 4-0 at this point in the season.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
The Bears are 3-0.

Stephen Ondra – NeHC – Senior Policy Advisor
Well, discussing NHIN governance, we're in the position that we're 15 months into a process of implementation, really, 9 months into our first implementation. We're working on a series of pilots around the country. Our first one was in San Diego with Kaiser Permanente. We now have a pilot up and running in the Virginia Tidewater area in Virginia and are in the process of going to the field to look at a variety of health information exchanges for ongoing pilots using the NHIN. That actual use in the real world, bidirectional exchange in a secure, authorized manner, has given us some practical experience on some of the good things that are going on and some of the problems that we have to overcome and so I want to talk a little bit about that today.

We've learned a lot and some of the issues or one of the goals of this; it's easy to get distracted on the goal that the goal was simply sharing information. That's not the goal. The goal is having information that can be used to improve patient outcomes. Now, if you share information, but it's not in a useable format, then you have accomplished very little, other than being able to measure the number of exchanges that occurred and you haven't really improved patient care, so it's not lost on us that the format that this is used in and can be consumed in and reused in is going to be very important.

We've also learned that there are several processes that have to go on that governance can address that are going to be critical to scale this beyond a pilot. Our goal is not a series of pilots. Our goal is the national implementation by the end of 2012 across the VA system with any provider in the private or federal sector that can exchange information with us using the Nationwide Health Information Network.

For some of that there are some critical needs that have to go on. One of them is the on-boarding process and how that on-boarding process occurs. There are going to be some issues that are national and some issues that are local, so talking specifically about governance, what should governance accomplish?

Number one: It needs to accomplish trust and secure information. Is the data real? Is the person sending it to us really who they say they are? Do we have confidence in the security of the system? It should have a simple and accurate on-boarding process. The standards should have a conformance that we can count on so when you receive data you can actually use it and count on using it. Privacy and security have to be the foundation of this.

Another question that comes up is, what are we governing? It's a rapidly evolving space. The Nationwide Health Information Network, the health information exchange space is evolving very rapidly. The one thing that I am certain of is what this space looks like today is not what it will look like in two or three years. If we settle on a governance that is extremely rigid and limits our flexibility we'll be making a mistake. We'll be in the endless process of being behind the curve, making rules that by the time they're implemented the space has already passed them by. So I think flexibility in governance is going to be very important. There are different entities and it's an unpredictable future.

Then the question of what are we governing is who governs this. What's the right model? Is the model that we have today—" We typically will look at command and control models because that's what we're familiar with, is that appropriate for a rapidly evolving space? What are the alternatives in governance that we should consider? I heard just before the lunch break some discussion of state versus national issues and I think there are differences. How do we define what are national issues that are appropriate for national governance and what then can be delegated to local control more effectively? We certainly see this in the constitution, right?

We're all familiar with this. There are some things that are better done nationally and some things that are better done locally. I think clearly defining what we want to govern and how we should govern that in terms of structure will help lead us to that right model. I don't have all of the answers to this, but I do know some of the questions that we've come up with.

So what are our current needs? Is the current model scalable? How is It scalable and to what? So, is the current model scalable to large health information entities, whether that be exchanges or provider groups? Is it appropriate for small, individual practices, large personal health records, individual personal health records? The same model surely can't apply.

When we look at how do we monitor that, how do you monitor large-scale information exchanges versus individuals exchanging individual information? One of the things that we're very interested in is would you do site visits? That may be something that you can do scalably to large entities, probably not to every individual in the United States that has a personal health record, to make a site visit to them. That definition can be pretty frightening; the health information police show up to check out your PHR. So we need to think those issues through, about what does the space look like. What role does the NHIN have in the space of health information exchange?

I think if we properly scope this to what does the NHIN (the Nationwide Health Information Network)—what use case model does this serve best? How do we see that use case model evolving? I think if we break down governance into use cases we'll be able to see through these issues of what's appropriate for national governance, what's appropriate for local governance, what's appropriate for personal health records, what's appropriate for large institutions and small practices.

Another issue is how well is the current governance structure working. What can we learn from it? What is going on in that governance that's something that's good and we want to preserve? What have we learned through using it that we would like to modify and change? I think that's something else that we should consider and then look carefully at those alternatives.

The last thing I want to touch on is once you have a governance model what do you do with it? Governance models make rules to help have fairness and adjudicate problems. What do you do once you've made a decision that something has fallen outside of the rules? You have a DURSA in place. What happens when someone is not following the rules of the DURSA? What entity does enforce actions and how is it enforced? Should that be the governance of the Coordinating Committee? Maybe. Maybe not. Do you have an outside authorization body or an accrediting body, something along the Joint Commission model? At what point does whatever body that enforces rules enforce them within NHIN, Nationwide Health Information Network membership? At what point is that turned over as a violation of law? Because patient security and privacy are the things that we have to respect most and there are already ample, legal protections for that.

So, thinking through the enforcement piece of that, an addition to governance is going to be an important thing that we have to think through. I don't know if I answered any questions, but from implementing this, the key things we've found is rapid on-boarding, the ability to have conformance, to enforce those issues and to look at how this space is evolving and is the governance model we have the right one in the rapidly evolving space and to preserve the flexibility within that to evolve with the space? Thank you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you. Paul?

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
Good afternoon, everybody. What I'd like to do is talk about the governance mechanisms that we at Surescripts have put in place that govern the relationships that we have with over 200,000 prescribers through 250 tech vendors, 52,000 community pharmacists, 6 mail-order pharmacies and over 25 of the nation's largest PBMs. As I think you all know, we operate the nation's e-prescription network that has connected all of these entities for purposes of e-prescribing.

To set the stage, I here this morning to talk about some of the principles that we have in terms of the network, so efficiency and better healthcare are certainly one of the primary purposes of HIT. Neutrality. Proper certification and interoperability. Quality. Improving the end-to-end quality of the entire e-prescribing process. Education in a collaborative environment. Core to each of these principles are obviously the concepts of privacy and security of the information that's transmitted across the network.

We have certain themes that are common across all of the departments in the company, ranging from certification, implementation, compliance, support, privacy and security, strategy, alliances and legal. One is industry stakeholder participation and feedback. That stakeholder feedback is vital to governing the network.

Transparency: Clear and transparent communications with participants. Consistency in the standards that we apply. Flexibility and responsiveness to change, because that was noted. This is a changing and will continue to be a changing environment. Then finally, enforcement of the rules that we have in place.

At the heart of our governance are some very basic questions. Who can connect to the network? What are the prerequisites and conditions for connectivity, including most certainly, security? How do participants connect? What are the standards? What message types can be transmitted? What are the conditions of continued participation?

What we've essentially done is establish the rules of participation, processes to disseminate the rules, programs to require compliance, programs to monitor compliance. Then processes to take enforcement action in the event of a breach.

We began with sort of the principle that we should operate a secure and neutral network in which all stakeholders meeting our certification and implementation requirements could participate with the assurance that their information would be transmitted accurately, timely and securely.

First, how do we establish the rules? We utilize the industry and develop standards as the basis for creating our certification and implementation guides. So our guides are developed based on the published standards, including NCPDP, HL-7 and X12. But in addition, we engage participants and other stakeholders through multiple outlets, including our biannual participant workshops, monthly participant calls, participant questionnaires and surveys and our advisory councils. For instance, we have workshops held twice a year to help us establish the rules for governance and trust by providing an opportunity for the participants on the network to receive education on impending changes to the network and provide them with an open forum to ask questions and provide suggestions to us. At last fall's workshop there were 176 executives and technical staff from 65 companies who participated in the network.

In addition, we also receive input via monthly participant calls. These calls are open to all of the participants and cover a wide range of governance topics from legal regulatory updates to technical and product developments and a review of the participant feedback that we've received.

We also have three stakeholder counsels, a strategic advisory council, a PBM counsel and a pharmacy counsel to ensure that persons with the knowledge and expertise in the industry have a forum to provide feedback to us.

Specific targets change based in the workgroup, but basically it's identification and resolution of industry concerns, engaging and participation by the participants and consensus building on operational and strategic direction.

We also have various mechanisms where we can receive feedback at any time from the participants, who may have suggested changes to standards and we then work with the SDOs or others in that regard.

Disseminating the rules: Once the rules have been vetted through these processes we disseminate our rules through our legal agreements, as well as various guides, such as our Network Operations Guide, our Implementation Guide, our Certification Guide and our Directories Guide. Additionally, we disseminate additional application certification, what are known as qualitative requirements, to participants to ensure trust in the quality of the transmission. These qualitative requirements are essentially workflow requirements that we impose that enhance patient safety by ensuring that the provider's clinical intent is fulfilled during the message transmission.

Once we've disseminated these requirements comes the process of requiring compliance in testing. So we have a robust certification process that tests each system connected to our network to ensure that all of the participants and the software they use comply with the guidelines and requirements set forth in our guides.

Of course, as an overall wrapper for our trust infrastructure, all participants must enter into a services agreement, which establishes the legal chain of trust that we have developed to ensure and protect all of the impacted parties. Participants must agree to certain requirements on behalf of both, themselves and any downstream entities with whom they provide services. So we require agreement to such things as authenticating and users, prohibiting advertising and commercial messages on the network, limiting uses and disclosures of data transmitted, preventing modifications to the software, continued compliance with the guides and, of course, compliance with all applicable state and federal laws, including privacy, security and laws related to breaches of information.

Finally, we monitor compliance with our rules of participation through an ongoing compliance program. The policy and compliance function is focused on certain principles, such as objectivity, neutrality, transparency, auditability and legality. So our team conducts both, regularly scheduled and ad hoc compliance checks as needed on the participants on our network. Ad hoc checks are initiated based on issues identified during daily operational monitoring of the network and issues brought to our attention by others, including through our support function. Regularly scheduled compliance checks are based on pre-established criteria to determine which participants will be audited. The checks may focus on any

number of requirements from our implementation and certification requirements, our security requirements and our contractual requirements.

Then finally, enforcement: If a compliance check results in a finding that there has been a violation of the rules of participation we send out a compliance notification, develop remediation plans, execute a decertification process and removal from the network based upon a participant's failure to meet the remediation plan and then execution of a reinstatement process if that participant wants to get back onto the network.

We specifically reserve the right to immediately suspend services and decertify a participant under certain circumstances, principally, if the issue at hand involves patient safety, privacy or security. We retain the right to immediately suspend that participant's participation on the network.

These are just a few of the measures that we've put in place and how we've implemented governance of the transactions that we have going through our network. I look forward to answering any of your questions.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you. Tom?

Tom Wagner – MedPlus/Quest – Chief Technology Officer
I'm Tom Wagner. I'm the Chief Technology Officer of MedPlus, a wholly owned subsidiary of Quest Diagnostics. My primary responsibility is for the strategic direction, the product governance and the product execution of our customer facing products, which includes the Care360 Product Suite, our data exchange services product suite, our NHIN Direct operations, as well as our ChartMaxx products. I would like to thank this body for giving me the opportunity to speak to you guys today.

First of all, Quest Diagnostics is one of the world's leading diagnostic testing. We perform testing services for 150 million patients annually across a connected physician network of about 160,000 physicians. First of all, I want to talk specifically about trust and how we've been able to gain trust of the network members.

We try to establish a collective vision with our stakeholders and then establish realizable goals. So we actually sit down with those different constituencies and stakeholders and map out a course for success. Keep them engaged the whole time, the whole process. Make sure they're on board at the time of requirement all of the way to the time of deployment with the product and then ongoing support.

With that, the Care360 Network, we engage multiple different stakeholders. Those include physicians, EHR vendors, health information exchange vendors, as well as payers and vendors. So it's a whole number of constituencies that we support. The trust doesn't come just with actually one implementation of that. It's repetitive and making sure that you're meeting the needs and the goals of those stakeholders. Stakeholders are ultimately important in making sure that they're satisfied and that their value propositions are being met.

The second part of trust we think is transparency and we really do hold up the NHIN Direct model on that. The NHIN Direct governance was established that not only was there multiple stakeholders from all different organizations in part of healthcare, including the EHR vendors and HIE vendors and the like, but it also included different stakeholders within those organizations. So the NHIN Direct governance wasn't through the lens of, say, a security architect or through the lens of a product architect or through the lens of executives. It was throughout the company and we all had a part to play in that transparent process. I think that's going to ultimately be rewarded with a very successful implementation of NHIN Direct.

That gets me to my next topic, which is really adoption and utilization as a criteria that the governance should really establish metrics on. We're all here to get people to use our networks and if we don't drive real stakeholder value with the adoption and utilization capabilities then we're just kind of wasting our time. So I would recommend that any governance that we have, that those things be included and

measured, not at the expense of privacy and security, obviously, but making sure that we can on-board people as quickly as possible.

The next thing is using the industry standards that are out there. Obviously, there are a lot of standards that are being written. Quest Diagnostics is a member of the ACLA, which works on specifications, including the recent addition of the Test Compendium Framework, also known as eDOS. We're also big supporters of HL-7 and LOINC. But those standards in themselves, there are a number of standards out there, they provide trust within the stakeholders that you're going to deliver information in a standard way every time. When you have a network as large as ours that's really important that each of the different stakeholders participate and we keep our commitments to them that we will uphold those standards.

The next is certification. That has to be a part of the governance, certification by all stakeholders. Obviously, there are different levels of certification for particular stakeholders. Obviously, the EHRs, there's been a concentration of work on standardizing those, but across the board HIEs, those kinds of things need to be standardized in different levels. I mean if there is a big implementation it can't just be the vendor certifies, but that implementation also needs to look at how they can get certified, because a lot of things can go awry in an implementation and you want to make sure that that stays on track.

We certify EHR vendors in our network on a consistency and accuracy of their reporting based on standards like CLIA, so we make sure that they go through a fairly rigorous process when they come up on our network and that we know that they're going to properly represent the lab results that are available.

Getting to some of the privacy and security areas: Quest Diagnostics spends a lot of time and effort establishing their security and privacy policies and they pretty much mirror what's going on in the healthcare industry. Consent management is one I want to specifically speak to. Within our Care360 Network physicians can message other physicians. They can send them clinical information. One of the mechanisms we've done for consent and I know this group has looked at many different consent models, but the opt-out policy by the patients is the one we've chosen for this particular piece because it works for physicians. Physicians are communicating with other physicians. If a patient decides that he doesn't want his information to be moved around, to simply set an attribute on their profile and that can't happen. So that gives them a level of trust. It's been good for the patients and it's been satisfactory for the physician and doesn't really inhibit or get into the way of exchange of information.

The second piece is roll based security. We're firm believers in that has to happen. You want to minimize the amount of access that any particular individual has. No one should be granted super user access to these networks and we need to really make sure that those levels of security are in place. We're not asking the government to define what those rules are, but certainly put in a framework that allows us to drive good behaviors there.

My final part is on interoperability. Quest Diagnostics creates and stores terabytes of lab data every year. That lab data is used for a number of different use cases and user stories, which include diagnosis, treatment, disease management, you name it, surveillance, those kinds of things, public reporting. So there are multiple stakeholders that are looking at this data and as ACOs and EHRs start to actually become much more popular HIEs as well, more and more people are looking for this data. They all have different purposes and they all need this data and they all have different purposes to look at it.

The problem that we're seeing and we're looking that this governance would have some framework to help us make sure that we're, as we provide this data to these different stakeholders, that we're, as content providers, not immediately becoming in a compliance issue with some regulation that's out there, whether that's CLIA, whether that's PCI or what have you, HIPAA, whatever the regulation may be. As the stakeholders start to increase we're starting to see more and more of that. Again, we're not asking for the governance to completely define it, but just give a framework where these different organizations can work with each other and the content providers on an immediate breach of some sort of regulation.

With that, I think we've implemented a very successful network. We continue to grow and we continue to add more policies and procedures as is necessary. I do thank you for the opportunity to speak and welcome any questions.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
As I was listening I was struck by a comment that Dr. Ondra made, which was—actually, you made it, but you don't necessarily have to answer it—that the governance structure should not be too rigid. So my question is, and all three of you can answer, what would that look like? What would be your fears that if you saw our recommendations you would look at it and say, "Those idiots. Why'd they do that?"

Stephen Ondra – NeHC – Senior Policy Advisor
It's a question I often ask myself. No. I think that what you would want to avoid is very rigid rulemaking that would set up a governance that could only be changed through very formal rulemaking, rather one that sets a broad scope and chooses to narrowly define what that scope is at this moment in time.

As you were speaking I was thinking about the constitution a little bit. I referred to it earlier and thinking about governance I sort of wander back to that and other articles. One of the things that's defined is that the powers are not defined for the Nationwide Health Information Network by governance are deferred to local control and then preserve the flexibility to redefine what those Nationwide Health Information Network governance responsibilities are. I think by clearly defining what are appropriate for national governance and then deferring for the time being all other responsibilities to local control helps you limit your scope, helps you create a governance that is a little bit more lightweight and maintains the flexibility for change that you need, ideally, without formal rulemaking in a space that's rapidly changing and evolving.

The other thing I was thinking that I wanted to add in my original comments and I'll take this opportunity is that governance is really going to be a very delicate balance. It needs to make safe, secure participation in the Nationwide Health Information Network easier and not more difficult, but it has to do this in a way that doesn't sacrifice a lack of governance that threatens security. That's always this balance, but one thing that's clear is right now there are far too many obstacles and far too little incentive in the nation to adopt health information technology and engage in health information exchange. We don't want to make governance an additional barrier, but we want to make sure that it does preserve security. That is probably the single most important thing that governance will do is ensure security of the system, because if you lose trust you've lost the system.

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
I'd certainly agree in terms of the comment about rigidity and the need for flexibility. I'll probably talk out of both sides of my mouth, sort of arguing both, for a national sort of rule on some issues and state flexibility on others. I think the states do need to retain a lot of flexibility, but I think we also need to recognize that a lot of the companies that are operating in this space are national in scope. I think some barriers that could come up is where you have different certification or accreditation standards in each state, let's say, around security. Some of these vendors or entities need to be certified by multiple entities around security to meet state requirements. You start creating, I think, some barriers in that regard.

I think another area that requires thought is the whole enforcement mechanism. Who is charged with enforcing various governance rules? Who has that responsibility? Is it the government? Is it others? Over whom does the government have jurisdiction? I've seen some issues arise where state legitimately want to impose some requirements on some entities, but don't have jurisdiction over those entities, so they go through the back door, imposing requirements on entities over whom they do have jurisdiction. I think you need to look at what you're trying to achieve. Do you have jurisdiction? Who ultimately is going to enforce those governance rules that you have?

Tom Wagner – MedPlus/Quest – Chief Technology Officer
Like Paul, this is a difficult issue, because you want some amount of rigidity, so as a software solution implementer there are an unlimited number of choices that we could go down in the ultimately flexibility that we could provide, but that costs lots of money to build out those kinds of systems. So the more

focused e can be on what things we have to have, what are the core, basic principles of what we need to provide so that we have a structural governance, but not, again, that fine line of not going overboard so that we can't build cost effective solutions. Quest Diagnostics is a large company with good financial resources and I just don't know how smaller companies are going to be able to participate in these exchanges if we can't give them some real good framework about what things that they have to do and then maybe in the future, kind of requirements. That's a difficult line, but I think some rigidity is absolutely necessary on a national network.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Wes?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
I'm going to start out by stating an assumption to get to a question I want to ask and if I'm wrong on the assumption tell me, okay? Paul and Tom didn't actually say who decides. They talked about all of the sources of input they look at to establish governance, but they didn't say, "Well, there's a vote of the stakeholders," or anything like that. My assumption is you gather all of that input and you decide. That's right. Okay.

We heard this morning about effectively two payment card, three payment card networks, which are effectively governed the same way. American Express ... through American Express network, Master Charge. Now, I think that that is a much more efficient and flexible way to govern, as long as it's in your interest to be flexible. It puts you in the position of being able to also decide on the rate of rollout of new technologies based on the ability of your clients to accept it.

Is there a model that we could use for Nationwide Health Information Network that would allow there to be several parallel implementer deciders so that none of them had a monopoly, but yet allowed for some flexibility and competition among them or do we need to have a single national and thereby, open deliberation kind of decision process for doing a governance of Nationwide Health Information Exchange? The question is for all three of you.

Stephen Ondra – NeHC – Senior Policy Advisor
I'll take a stab first. I think making sure that, again, we bring the stakeholders and get them involved is important. You're right in your assumption that we then homogenize that information and come out with a governance that can work within our compliance and rules.

The question I think you asked is can we have multiple implementations of kind of separate governances that can work across the country. Is that, in essence, the question?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Yes.

Tom Wagner – MedPlus/Quest – Chief Technology Officer
I think the answer is yes. I think we're starting to see that as the state wide HIEs start to turn up here, as more ACOs start to appear. I think that is happening, but again, getting some alignment with those governances that they're at least on the same page with each other would be extremely preferable for a large network. I mean that's the issues that we're getting twisted and turned with different collisions that happen because different stakeholders have different objectives and different value drivers. So we need to make sure, again, that we can provide those stakeholders with real value without compromising our regulations.

Again, at the end of the testimony was getting to what those really are so that we can establish the framework. I always think what are the top five or top ten things that we have to do, that everyone has to adhere to and then you can let the other groups or the individual HIEs kind of then determine the rest of what they've got to do.

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development

I think, first, I'm going to modify my answer to your assumption. We don't decide everything, so standards are driven by standards organizations. Privacy and security laws are driven largely by law, state and federal. So there is a lot that I'd say we don't decide and that we certainly build on.

I think the issue you raise is the need to have flexibility and to encourage innovation, so I think different networks can bring different value propositions to their participants and go beyond just the minimum of standards, as articulated by some of the SDOs. I would think that you would want to encourage a governance structure where maybe certain essential elements are standardized, but to still allow networks to be created that can respond to the needs of participants, create value added, whether it is, for instance, I mentioned qualitative requirements that we impose that are really our view as rules that enhance the security and quality of the messages. So I would suggest that you can have multiple networks and should encourage some multiple networks for those reasons.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Before we ask Dr. Ondra, I'd like to check a proposition with you. I believe that your compliance testing that you do represents interpretations of the standards where other interpretations might have been acceptable and interpretations of the law where other interpretations might have been acceptable, so to a certain extent, even when you rely on an outside organization you end up making decisions within the parameters of those things, right?

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
That's probably a fair statement.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Okay. Dr. Ondra?

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
A ... statement, but a fair one.

Stephen Ondra – NeHC – Senior Policy Advisor
Well, I've had the advantage of listening and so I'll take that advantage. As I listen to us talking about this, one of the phrases that stuck out was this desire for individual autonomy to some degree, but you get down to this point of some alignment of governance would be desirable. What you're really talking about is at the edge of the networks as they have to talk to each other you need some sort of alignment. That really does imply some sort of national governance that decides issues that are appropriate on a national level to allow these entities to actually speak to each other and avoid a fragmented tower of babble sort of evolution.

That gets to, again, this desire of how do you keep any kind of national governance consortium appropriately scoped to issues that are appropriate to networks being able to talk to each other and to the exchange of information and then only having those things as a part of national governance. I think that any model that preserves that will avoid this very restrictive approach to governance that will become an obstacle. It may eliminate development and innovation, but if you make that a little bit too light you start to harm security conformance, the ability to exchange. So defining those things that are appropriate and best suited to national decision making and then finding whatever federation or consortium or governance model is appropriate for those decisions, bringing in the stakeholders and then letting the decisions that don't require that be done locally, I think, will help get to that balance that's needed to keep the space dynamic, but also usable and secure.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
So sort of Thomas Jefferson with steel boots. Thank you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
John.

John Glaser – Partners HealthCare System – VP & CIO

A quick comment on the last interchange and then a separate question: The quick comment is to your question, Wes, about is there an analog in the healthcare world for the three or four autonomist functions. I'll do the same thing you did and state an assumption first to see if it's valid. Is Mark still here? He's gone. Okay.

My assumption was that the autonomy of the four financial institutions have had their own governance authority was coherent with their scope of transactions within a credit card line; whereas, in healthcare one's data is transferred from one ... to another. It becomes the weakest link phenomenon. So I would suggest that there is this fundamental difference in the financial environment versus the healthcare environment vis-à-vis your question related to the weakest link and that the risk of a breach becomes, obviously, vulnerable to the weakest link if there are four separate governance entities or mechanisms in healthcare similar to how there would be in banking. I don't know if you have any thoughts about that.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Well, I think, as always, you have to be careful in drawing analogies between healthcare data and financial data, but on the surface it seems that if some information is transferred from one place to another there's always the weakest link problem. I don't automatically see anything that distinguishes healthcare from financial transactions in that manner.

John Glaser – Partners HealthCare System – VP & CIO
Okay. So we can maybe debate that more off-line. My question for the panelists: Paul, you made a statement that really intrigued me and that is that you said you could immediately terminate participation of any one of the participants based upon an indiscretion on their part. I have a series of questions about that.

How often has that happened? Is there a trend? Are there things that account for the trend, either up or down? Finally, if you have repeat offenders, what escalation do you have for repeat offenses?

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
So, one, define indiscretion: I mean our focus is on patient safety issues, privacy and security, so to define that a little bit more. I didn't bring statistics with me. It does occur. We have found where a software vendor may change its code and not submit for recertification and that code change has an unintended consequence. An example: It has the unintended consequence of cutting off the Sig, the instructions on the prescription. So it does happen. As I said, when we are advised of it we immediately take steps to cease that connectivity and do not let them back on until they solve the problem to our satisfaction and become recertified.

Is there a trend? It's probably too early to say whether there is a trend, but we are increasing our focus on working with all of the vendors proactively so that it doesn't happen, to ensure that they come and get recertified if they make changes to their software. So my hope is the trend will be downward and not upward.

What was the other question?

John Glaser – Partners HealthCare System – VP & CIO
Repeat offenders.

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
Well, we haven't had any yet, but certainly, if we did I suggest we would contemplate not even going into a remediation plan, but saying, "You don't meet the rules for participation," but we've not had that issue as of yet.

John Glaser – Partners HealthCare System – VP & CIO
Thank you. I have this sense that for years to come the NHIN will be this collection of eclectic networks and some will be, Paul, like you and Tom, which are dedicated to a particular class of transactions between multiple stakeholders. Some will be RIOs. Some will be like the VA, which deals at a national

level. Some will be RIOs. Some will be two hospitals, who have a joint oncology program and want to move data back and forth. It will be highly eclectic across the board here.

In each of those cases there will be a need for the kind of governance that you guys are talking about; monitoring, certifying, enforcing. I've noticed that if you don't the darn thing doesn't work and you actually can lose customers as a result or trust. If I don't trust on the PBM you'll get mine, so there's a class of governance that is just good management, governance in a sort of broad use of the term. It's not clear to me that that governance is inherently the same as the governance that existed at a national level. In other words, one shouldn't extend it just automatically into this is the kind of stuff that has to exist at a national level and particularly couple that with the sense that this could be fairly embryonic. It is embryonic right now, highly evolutionary. We can talk about innovation. The flip side of innovation is dead ends and mistakes that will go on for years to come.

A sort of theory could be all of those who implement in this sort of eclectic species need to do exactly what you guys are talking about, but at a national level it needs to be very parsimonious and only in two areas. One is standards, as good as we can about the exchange and as well as we can. The second is protecting the trust of the patient to make sure that the data is not misused in ways that they find highly problematic. That's it. End of regulation. Those two areas.

You could have and say I want to learn as we go along, so we'll form a group of folks, who perhaps are represented by you all and others, who say as we go along and we understand better that this eclectic narrows to a smaller set of models, a mature set of models, we'll then be smarter about anything else we need to do along the way, but for the time being we're just going to be very spared, knowing that certain governance has to occur at the local level, but it would be a mistake to try to have a national certification body, because nobody is proposing, I don't think, to operate a national NHIN where they operate in the sense that you guys operate this kind of stuff. I'm just curious about the reaction to that. It's sort of a very spare national approach that goes only in two areas with some learning processes along the way.

Stephen Ondra – NeHC – Senior Policy Advisor
I always feel like I learn something when John talks. I always enjoy that, even in a question.

In terms of government management models, I agree. Standards and trust, those are the cornerstones that have to be accomplished. The other issue is as you scale this, I spoke earlier about what are the appropriate governance models of scale in terms of where you started with this, which is the management part of governance and who does that. I can think of three types of entities. There are public/private groups, such as this. There is a federal entity and then there's an accreditation body. How do you manage this when it becomes large scale? I'm not sure that a federated group, such as this—I'm familiar with the sort of volunteer or relatively volunteer groups. They don't manage things extremely well when they get to scale, because it requires structure and it's a full-time job. You need something that can do that, somebody that's certified to the point they're expected to accredit, accredited to manage is the model that we've seen elsewhere that works very well. The federal entity, I'm not sure because the federal government is one of the stakeholders.

John Glaser – Partners HealthCare System – VP & CIO
Steve, what I wouldn't do at this point is have a national accreditation process. I mean it's too early.

Stephen Ondra – NeHC – Senior Policy Advisor
Right.

John Glaser – Partners HealthCare System – VP & CIO
You'll have to accredit because you've got to make sure people know what they're doing and this, that and the other—

Stephen Ondra – NeHC – Senior Policy Advisor
Right. When you look at accreditation bodies what they usually have is some sort of accrediting that accrediting the accreditors and this spreads out so the accreditation goes on at a more local level. I

agree with you. You just want to make sure that the people accrediting on the local level are accredited themselves. So what you want is a very broad pyramid, not a lot at the top, a lot going on on the outside, but something that's making sure that what's going on at the base is what's supposed to be going on. So how you house that is, no doubt, in many discussions, but it doesn't feel like a federal entity and I'm not sure that a committee is the right structure, but some sort of body that can really manage the management part of governance. Are things going as they should be? Are people following the rules? Are there errors going on that we ought to know about? How is that being brought to attention? You can look at how do you adjudicate that.

Deven McGraw – Center for Democracy & Technology – Director
Throughout the day today and this panel also testified to this, nearly everyone has agreed how important privacy and security is from a governance standpoint, so it won't surprise you that my question has to do with that, which is we actually have governance of privacy and security in some shape or form, right? We have laws. We have a set of rules and requirements under the HIPAA Privacy and Security Rules. States have acted on privacy and security in many ways. So, if this remains an issue for the Governance Workgroup to consider what do you all think needs to be done above and beyond enforcement of the law that we already have, maybe in terms of substance, but actually more importantly, in terms of mechanisms in process.

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
I'll take a shot at it. I mean, as I said earlier in response to the earlier question, you're right. Privacy and security is governed by federal and state law, so I don't think that we or others have a lot of leeway in determining what the rules are there. I think our function is, one, to create the framework to ensure that they're complied with. It could be as simple as ensuring that everyone who connects to us meets the security standards and certifies with a third-party auditor to that effect or to do more than what is required by law, quite frankly. So obviously, people have the flexibility to do that.

I'm not sure I have a direct answer to your question, but what I think I would say is that everybody says it's important because it is important, but I think to your point, there are laws. I think where people, where more attention needs to be spent, not at the sacrifice of privacy and security or other issues around quality of the messages, because there you don't necessarily have standards. You can just have a technical standard in privacy and security, but that doesn't mean you've got a quality message going through a network. So I think issues around quality and patient safety require a lot of attention.

I haven't answered your question, but that's my thought.

Deven McGraw – Center for Democracy & Technology – Director
It wasn't meant to be a trap, because, i.e., say there's nothing more to do and then I come back and say, "Well, we think there's more to do." I mean I am actually thinking about even in terms of the recommendations we're making in the Privacy and Security Tiger Team where we certainly take law as a baseline, but think about whether there are specific gaps and what more might need to be done in order to reach that trust foundation. I consider the Tiger Team to be working on the substance, but then what is then the mechanism if part of what you're saying is a set of best practices that are certainly not below the law, but are good behavior that if all you're aiming for is strict compliance this would be a level above that.

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
I'd like, if I could see one thing that could happen, getting back to John's trust at a national level, the two basic things are standards and trust. The trust on privacy and security, if there could be some ..., if you will, amongst the national and the state side. I know you're laughing, because it's a difficult thing to ever get to, but it would make interoperability a much more feasible and tangible thing that we can go after. Without that it's still doable. We still figure ways out to make that happen, but it becomes much more difficult for us to execute on that. I know it, but if the national—

Deven McGraw – Center for Democracy & Technology – Director
I hear you. I'm not sure we can fix the problem, even if I assumed I agreed with you that it was a problem, but—

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
Yes. To your point, we do have laws already that are on the books and we are all working and executing those laws so we can figure ways to make it happen, but if I had my total wish that would be the one thing that we could do.

Stephen Ondra – NeHC – Senior Policy Advisor
Yes. In terms of the specificity, cyber security is not my area of expertise. I'd be better straightening out your spine if you have scoliosis, but lucky for you you don't. But I'm sure of a couple of things. Number one, you can learn lessons from other networks that have been set up that didn't bake in privacy and security at the very foundation, because when you go back ad try to do that it's very difficult. If you lose that on this you're going to lose the network and so this has to be. This community has done , really, a very good job since I've been here at being forward and leaning on this issue.

I've been to far too many meetings where this is a difficult issue and so it's put off. Let's deal with that another time, because that's a really hard one. You have to take this hard one on right now. I think this committee has done a really very good job at leaning forward on that. I think we have to because trust has to be at the foundation. The standards won't matter if there isn't trust. Right after trust comes standards. I agree with John. But they're in that order because if you don't have that the network won't work and then you'll have to defer to something else of personal control.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Jodi?

Jodi Daniel – ONC – Director Office of Policy & Research
I'm trying to think about in this space, the proper role of the federal government versus the state and private sector, other different entities. ... from the questions of John and Deven, so just thinking about security. Through their standards development organizations they're talking about security standards. Your organizations have developed or adopted policies regarding security that you impose on your participants.

We heard the credit card industry talking about exactly that, where they had their own security policies and then they all got together and said, "How can we? We have slightly different policies here. What can we do to bring these together?"

My question is are there already mechanisms in place, both through standards ... organizations, through industry collaboration, as what was done in the credit card industry, to bridge some of those variations and to come to some consistent approaches to dealing with security and trust or does the federal government need to step in on some of these issues, because there are too many diverse stakeholders. There are too many different types of networks and entities that are exchanging information. It isn't just four entities, like in the credit card industry where they can get together, think it through and come up with some approaches to dealing with this and have industry voluntary compliance.

Is this a place where the federal government needs to step in and in what role? In setting up a process, in establishing standards? What do you see as the appropriate role for governance and the federal government on these issues versus where we should kind of step back and let things develop?

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
... federal government. Should the federal government step in? No, in a word; I think the federal government should be a participant in the discussion among the different stakeholders. One of the things I said earlier was that we want governance to facilitate safe and secure membership in the Nationwide Health Information Network and not to become an obstacle. I think unless the federal government is involved in a dialogue with all of the stakeholders, it's far too easy to create rules and regulations that have unintended consequences and become a barrier in this space. So I think that the federal government has a responsibility to participate in those discussions, to fill any gaps that can be filled elsewhere, to step up when that's needed, but to make that step a very light step—

Jodi Daniel – ONC – Director Office of Policy & Research
But do you think that there can be the kind of industry collaboration in the diverse market that is kind of; I don't remember the eloquent day job described it, words he used, of sort of a mish-mash of different kinds of entities that we have. Is that kind of collaboration? Can we expect that to happen without kind of the push on the federal government?

Stephen Ondra – NeHC – Senior Policy Advisor
I've seen it happen in a couple of examples. Number one, this committee has pulled people together is a great example. The Nationwide Health Information Network Direct project was a good example, where you had the federal government bringing stakeholders together to work through an issue. I think when it comes to security and privacy it's important to have all of the stakeholders there. That will be industry. It will be patients. It will be providers. There will be payers. I think that you do need that representation. I think you can work through that.

You do need leadership and I think leadership is an appropriate place for the federal government, but in terms of the sole decision maker, I don't think that is an approach that will get us the result that we would like.

Tom Wagner – MedPlus/Quest – Chief Technology Officer
I'd like to say I think we have kind of an incubation of it with NHIN Direct. I think that is a group that has had multiple stakeholders involved in creating those standards. I think we're close to piloting that and I think also organically we're, as new HIEs, ACOs start to pop up we organically having to do what you just suggestions, which is work together and figure it out and roll up our sleeves and say, "These are all of the privacy concerns that we make sure we handle from a Quest Diagnostic standpoint. Here is your list. Let's figure out he we can mesh those together. That happens almost every day with different HIEs.

Now, having some established, national capability and I think NHIN Direct, again, will give us some of that I think will e very beneficial for us to really begin an era where we can move data from really any entity to any other entity in a secure and private manner.

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development I'm sorry. You started off and you said that we have now an incubator and I didn't catch—

Tom Wagner – MedPlus/Quest – Chief Technology Officer
In NHIN Direct. With NHIN Direct I think we're incubating that process, that governance with different stakeholders. There were a significant number of stakeholders. Again, I want to emphasize it wasn't just through a technology or a security lens. It was through the value lens as well.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Paul, did you want to jump in on that one?

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
Well, I guess I would just repeat the comment that I made earlier. I think it depends on the issue, Jodi. I mean I think the federal government has already done a great job in creating collaboration and getting organizations to collaborate and talk, but I do think it depends on the issue. I think that I'll go back to my innovation comment; that entities, whether they're vendors, networks or otherwise, need the ability to innovate and respectfully, sometimes the federal government doesn't move quite fast enough in that regard. So I think it depends on the issue. Privacy and security, I think, is an easy one. Others, where it's appropriate I think entities will come together and collaborate. That's happening now. I think it's a part of healthcare. It's almost unique to healthcare in some respects, so I think it depends on the issue.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program

I think one of the things that I know I struggle within these conversations is the sort of skilled question governance of what? You each sort of run and operate a network, if you will. The question of what does governance mean to your network, I think is a little bit tangential to the question we need to be asking. Maybe the question is how do you think about governance in the context of your experiences, obviously, from your own vantage point.

How do you think about governance? Do you think about the role of government any differently when government is directly paying for us through grant funding, information exchange or incentivizing information exchange or interacting in information exchange? Do you see the role of government any different in that context? ... the role of governor in that way. I mean I'm just thinking about sort of paying for some of these things and thinking about both, some policy perspectives; you've talked about privacy and security and also from an enforceability and accountability perspective. Do you think about any of these elements differently?

Paul Uhrig – Surescripts – Chief Privacy Officer, EVP Corporate Development
I think any time you're paying you have a say in what you're getting. I think that's true. I don't think though that that would be the driver. I think it's just making sure that our networks aren't compromised and having the trust of those stakeholders. It means more to us than anything. If we lose that trust, if we produce bad results or give fictitious results to physicians ... get the patients that's awful and is not acceptable. I think that trust in the security of our networks means more to us than anything else.

We look at each of the different policies and security policies and privacy policies that are out there and we have teams of folks that make sure that our products are always in compliance with those pieces, but then there are , specific to the lab industry, things that we have to do to make sure that our networks aren't compromised. So I think that's more of a driver for us than having to say we're with it, but I think the government, if they are sponsoring these networks and are funding those networks, should have some basic level of trust and security that's out there. Certainly, content, governing the content; that should be something that can be mandated as well.

Stephen Ondra – NeHC – Senior Policy Advisor
It's a great question. It kind of gets to what's the government's role all of this. The government has 3 or 4 different roles in this, frankly. The first role is ensuring the well being of our citizens. Why does government fund this? That would be number one, right? That's the job of the government.

Number two: To be a facilitator of innovation that's going to benefit jobs and the economy as a whole as you create the health information ecosystem. That's an important role for government and why we fund this.

Number three is a payer of care and the benefits in that. So I think the government has all three reasons to be involved in this. As a payer we certainly deserve to be at the table with others that are involved in funding, health information exchange. As the insurer of the well being of our citizens we should be there to make sure that's going on and as the government is trying to innovate and create jobs and create a health information economy we need to be there for those reasons.

So I think for all of those reasons the government should be a part of that discussion, but to keep that discussion innovative it can't dominate needlessly. It has to be a collaboration or discussion between the stakeholders. I think the fact that the government is involved in grants and awards and servicing this comes from all three of those purposes, economic and social responsibility and economic innovation, so I think for all of those reasons it's appropriate for government to fund part of this and then to quickly, as the economy takes that over, back out any federal funding beyond what's appropriate.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think we are moving a little bit ahead on our schedule. I'd like to thank the panel. They were very insightful and if you have any additional thoughts or questions you'd like to send to us we'd appreciate anything that you can send to us via e-mail on these issues.

We're going to do a slight change in our agenda. Laura has agreed to do her part at this particular time slot. Then we'll move into panel four at 2:15, which will be on schedule and that will leave us a little bit of extra time at the end for panel discussion. Also, recognizing that some people may have to leave we want to make sure we have as much time as possible towards the end of the meeting. Thank you so much, Laura, for being flexible.

Laura Adams – Rhode Island Quality Institute – President & CEO

I'm Laura Adams. I'm the President and CEO of the Rhode Island Quality Institute in Providence, Rhode Island; Faculty of the Institute for Healthcare Improvement in Boston, Massachusetts; Chair of the Board of the National e-Health Collaborative in Washington; and Chair of the Institute of Medicine's Planning Committee for the Electronic Infrastructure for the Learning Healthcare System. Mary Jo Deering and I decided that I wear so many hats that I'm becoming a human hat rack.

With that, I want to thank you for the opportunity to address this panel. I've been asked to do so today to share with you the work of the Institute of Medicine and the planning and efforts that have been going on since April to take a look at the electronic infrastructure for a Learning Healthcare System. Many of you know that the IOM has had a series on the Learning Healthcare System for quite some time. This workshop series was initiated at the request of the Office of the National Coordinator for Health Information Technology. We have had references to this in the past as element three. When we think about it, element one was adoption of technology, element two, meaningful use and element three, really the full realization of the promise of health information technology and all that it entails.

This Committee was convened in April of this year and it is responsible for the series of workshops that are important to the capacity of a Learning Healthcare System for the continuous generation of new knowledge, improved care and the advancement of population health. Some of you that have been working in quality improvement for some time recognize this as the idea that every patient or every care encounter will contribute to improved care for all of those that follow. Those of you that have been busy working on quality improvement initiatives where you're gathering the data and you know from each experience that you'll take that back, due plan, due study ... small scale test of change to continually improve that over time is really the basis for the work that we're looking at here. How does this health system both, deliver care and improve itself continually?

The series of workshops have been conducted in July and September. They'll conclude on October 5, 2010 and we've been assessing the technical policy, governance issues and priorities addressed in using an interoperable, electronic infrastructure, whose foundation and evolution is guided by meaningful use standards for transformative insights and progress. I would point out to you that my sense of the essence of this work is that it has a particular focus on the infrastructure required to advance research and quality improvement capabilities. A summary of this series will be published by the IOM with a target for a preliminary publication by the end of the year. The work being done in conjunction with the IOM EHR Innovation Collaborative, so this is an ad hoc convening activity under the ... of the IOM Roundtable; this electronic health record innovation collaborative brings together representatives from different organizations using EHRs from different vendors. In general terms, the intent is to identify common issues and interest and to explore collaborative and coordinated projects that can facilitate the contributions of organizations using EHRs and advancing the frontiers of the Learning Healthcare System.

I just want to share with you a little bit of the objectives of this workshop series over the summer. One: To foster a shared understanding of the vision for an electronic infrastructure for continuous learning and quality driven health and healthcare programs. Two: To explore the current capacity, approaches, incentives and policies and identify technologic operational, organizational policy and implementation priorities. Three: To discuss the characteristics of potentially disruptive, breakthrough technologies. Four: To consider strategic options and priorities for accelerating progress on the approach to the infrastructure and moving beyond, to a more seamless learning enterprise.

The instructions we were given at the beginning of these workshops were to make no assumptions, to essentially start from the idea that we could go in any direction we pleased with this; that there were no

restrictions on us from the beginning. As we evolve over time we're increasingly cognizant of the need to be aware of our surroundings and those initiatives already in place and think about how these might be integrated with, coordinated with or built upon.

I would suggest that one example of the potentially disruptive breakthrough strategies is that we had a conversation at our last workshop in September where we began to have a very sharp focus on ultra-large scale systems. That focus was such a large and intense focus that the word breakthrough, in our own, collective thinking, was used so many times that it was almost unnerving in the meeting; that there was that much consensus around the idea to explore the ultra-large scale systems as they pass forward for this. So I would just suggest that that's one of the things that you can expect to see coming out in the IOM report at the end of the year.

There were several issues that have been motivating this discussion. First of all, the rapid development and information technology that are substantially facilitating the potential use of health data for knowledge generation and expedited application of new knowledge for clinical care. As we all know, the IOM study that showed that we had 17 years when new knowledge is generated by science before it gets propagated through the system and benefits patients is shocking in a society as sophisticated as ours.

Policy initiatives that we'll lead in the near future to the electronic capture and storage of virtually all clinical data, as well as data from several related areas of health; healthcare, public health, clinical research, to realize the system's full potential for individuals and populations. Promising potential and federated distributed approaches that allow data to remain local, while enable querying and pooling of summary data across systems. Ongoing innovation and search technologies, with the potential to accelerate the use of available data from multiple sources for new insights. Meaningful criteria and health reform provisions that provide starting points and incentives for the development of a learning system for quality improvement and population health.

While underscoring the need to be strategic on issues and opportunities, while maintaining flexibility to accommodate breakthrough capacities and the need for attention to limiting the burden for health data collection to the issues most important to patient care and knowledge generation. Requirements for governance policies that foster the data utility for the common good that cultivate a trust fabric with the public and in between data sharing entities and accelerate collaborative progress. Lastly, availability of standards for the aggregation of large pools of data for purposes such as clinical effectiveness research, biomarker validation, disease modeling and improving the research process.

In closing, I'll just share with a few elements that have been coming out of this discussion that you might not be surprised to see in the report. The governance concepts that are currently being advanced in the workshop series and are being given serious consideration include such things as making use of complexity theory to guide the governance development, governance structure. Some of these understandings of principles of complex, adapted systems include such things as simple rules, governing very complex behaviors.

You heard it many, many times today; the idea of a small set of really strict and immutable principles or rules that beyond that there can be local innovation or local adaptation of those types of things, but those particular rules themselves are immutable. The accommodation and invitation of constant evolution, so part of the complex adaptive system principle that we're using and the transition of paradox, so the idea of a governance structure that gives direction without giving directives, that maintains authority without having control That idea is some of the things that we're building in and thinking about with this, taking sort of a both end approach to preserve the elements necessary for engendering trust, effective functioning and the achievement of goals, while permitting sufficient flexibility to encourage innovation.

Again, we want to foster governance at a basic level of immutable principles shared by all that allow for local action and innovation that's enabled and guided by the principles, while still upholding them. So we want to think a little bit about the identification of stakeholders with interest in a governance and electronic infrastructure, considering a both-end approach to stakeholder engagement, to balance that need for a very, very broad engagement, while understanding the very real practicality required for agile and

effective decision making. Considering the role of the creation of incentives to elicit stakeholder behavior consistent with the principles and goals and incorporating stakeholder input into the design operation and evaluation of the governance function to evoke initial and ongoing support.

Leverage work already being done to address similar governance challenges. The work that we're interested in leveraging and working with, those specific to health IT, such as the Beacon Communities, the regional and state health information exchanges, the ONC, health IT Policy Committee Governance Working Group, Markle, caBIG, Sentinel. Those are just a few of the examples and other industries and areas such as these on the Internet.

Identifying key aspects to be governed or … you've heard many, many times today. Privacy and security protections; articulation of the value proposition of all stakeholders; commitment to the common good; the legal, ethical, and policy framework for operation; coordination with other key initiatives, including the federal, state and local government as well as private entities. Promotion of the full use of the system to achieve a wide range of goals consistent with the principles, an evaluation of the performance of the governance function including the establishment of an evaluation mechanism at the onset to communicate intent and set expectations. Creation of metrics to evaluate the level of value being delivered to participants and stakeholders; creation of mechanisms to evaluate the effectiveness of the governance structure in maximizing the use of the system in the context of a high degree of adherence to the principles; and finally, the continual improvement of the governance function based on the results of the evaluation. We're producing in a set of recommendations that will inform this strategy for this creation of the electronic infrastructure for the learning healthcare system. I will be happy to take questions at this point.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Mary Jo?

Mary Jo Deering – ONC – Senior Policy Advisor
Laura, you and I had a brief conversation about this before and I just wanted to tease out of what you said one thing that I would like to emphasize my understanding. In your concept, you are assuming participants in a particular system. I mean, that's sort of the language that comes out when you say the participants in this learning healthcare system and you are talking about a governance structure for them. That was what prompted the inclusion of lower here is that such language, which could easily lend itself to the concept of a stand-alone network. So I wanted to ask both a clarifying question and then state an assumption that you and I have sort of shared, but just to be clear.

First of all, am I incorrect in sensing that your report might actually assume a set of particular agreements among a constellation of organizations at some point in time that would be building a conscious collaborative learning system? Or are you talking more generally about what is needed to knit together any organizations with mutual interests who wish to share information? My sense is it's the latter in that the goals are such that we would be able to extract information easily across large, large bodies of data and information—the more the better, in terms of our ability to extract knowledge from that to use that to rapidly produce new information and new learning for the system. So, by nature, if that were restricted to just a few organizations, we've defeated our purpose. So that's what's I thought, but I wanted to clarify.

Then the other clarifying point was that in our discussions, the working assumption is that we would all have failed if what emerged through rulemaking for governance in the next 18 months did not in fact take care of 90-X% of the needs of such a learning healthcare system. Is that a correct statement? In other words, that there may be a Venn diagram of governance needs, but it will be very largely overlapping and that perhaps there might be only a few unique governance functions or attributes that might be needed to enable the type of exchange that you're envisioning.

Laura Adams – Rhode Island Quality Institute – President & CEO
I would agree with that. When I think of what some of those really unique needs might be— When I think about issues of research, there might be particular issues such as need for governance around publication. How do you attribute when the data has been ...? So there are types of things that we might

look at that are specific to that context, but otherwise, from what I've talked about today—all the work that we've done over the summer, the testimony today—I'm not hearing anything more than about a 3% to 5% lack of overlap.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I think I just have one question for clarification. It pertains to a panel we had some discussion on earlier from New Mexico. That is where do you draw the line between research and learning? That, I think, has significant implications for governance in that part of the way we've been trying to divide it—of course, when you do quality improvement, you learn things, but that isn't necessarily research, even if you publish the results of your quality improvement initiative. So have you had those kinds of discussions?

Laura Adams – Rhode Island Quality Institute – President & CEO
I'd have to say that I think there's almost a tectonic shift happening in our definition of research and how we learn. I think that we have, over time of course, looked at the gold standard, the randomized clinical trial, as one of, perhaps, the only way to learn. It's what gets you into an adjudicated journal. You certainly have to follow a great deal of rigor.

I think what we've now begun to understand is that there is an enormous amount of learning that can only take place in the contextual application of principles, concepts, the actual changes. How do we function in the real world? That actually can't be discovered by our old methods of research. The only way that we can learn about those has to be as they play out in the context of the real care delivery that goes on, the real attempts at maintenance of health. That that ability to collect up that ability of that information about how it's really playing out is going to be incredibly important over time.

So while I still see a tremendous role for our traditional definitions of research, I think that idea of switching from an analytics/statistics base of learning—of group A compared to group B—to rather an enumerative basis—a group A to group B to an analytic. Looking at my group of patients over a period of time as I apply this new knowledge, are my patients getting any better last year compared to this year? So that idea of a new mechanism for generating knowledge. It's something that I see us gradually accepting in this country. As you've seen our difficulties we've had in our conversations of should this go through an IRB or not. Those are exactly where those conversations are playing out right now because I do believe it's a new mechanism for learning that deserves as much respect as our traditional methods.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Unfortunately, we only allotted a small bit of time for this. So, if you'll save your questions and comments, we can come back to this when we have discussion. We're going to move on now to panel four.

In this panel, we're looking to identify the scope and implementation of existing authorities that will or might assume responsibility for some aspect of governance. So we have Loretta Garrison, who is a Senior Attorney in Bureau of Consumer Protection, Division of Privacy and Identity Protection in Bureau/Consumer Protection at the Federal Trade Commission. We also have James Golden, a State HIE Governing Authority and Director of the Minnesota Department of Health Division of Health Policy.

We have Doug Fridsma— Did I do that right? Close? Okay, good. Doug is with Standards and Interoperability Framework and the Acting Director of the Office of Interoperability and Standards at the Office of National Coordinator, and Michael Matthews, in a different role, from the National Health Information Exchange, formerly NHIN Exchange Coordinating Committee and Chair of that.

So we'll start of with Loretta. Thank you for coming.

Loretta Garrison – FTC, Bureau of Consumer Protection – Senior Attorney
Thank you very much for inviting me today. I need to say first that I am here only to speak on my own behalf. I'm not here representing the official views of the Commission or of any individual commissioner.

As you mentioned, I'm with the Division of Privacy and Identity Protection at the Bureau of Consumer Protection at the Federal Trade Commission. This is a relatively new division that was created about five

years or so ago that reflects the growing importance of the privacy and security issues facing consumers. As you may know, the FTC has been very active in privacy and security issues, in particular online, of late, since the early 1990s.

What I'm going to cover today, or I've been asked to cover, is a fairly high level overview of the FTC statutory authority, our work in both data security and privacy. I'll also briefly discuss the FTCs Exploring Privacy roundtables that we held earlier this year and the lessons that we learned from those events.

First of all, the FTC is a consumer protection law enforcement agency. In our area and privacy and data security, we have several primary legal tools at our disposal. The first one is the Section Five of the Federal Trade Commission Act. This gives us authority to enforce against unfair or deceptive acts or practices in or effecting commerce. This is a very, very broad statutory mandate. There are some exceptions from our authority such as nonprofits, financial institutions, and the business of insurance and common carriers. But otherwise, we touch many different types of industries including, as you may know, certain health providers.

The deceptive prong: We focus on misrepresentations that are made to consumers. So if you say X but you do Y, then you have made a deceptive statement and you're subject to our enforcement. The unfairness prong is if the act causes or is likely to cause substantial consumer injury, which is not reasonably avoidable by consumers themselves and which is not outweighed by countervailing benefits to consumers or competition. We have used both of these prongs in our privacy and data security cases.

In addition to that, we have some very specific authority under the Gramm-Leach-Bliley Act to enact a safeguards regulation and apply it to a category of financial institutions, which are not traditional financial institutions. In this area, we work jointly with our fellow regulators in the banking industry or the banking regulators. There, we have a mandate to set out administrative, technical, and physical safeguard requirements. Our standard that we apply in this area is reasonable and appropriate safeguards to protect sensitive information from unauthorized access reviews. This is a standard that's scalable and flexible. It's actually very similar to HIPAAs legal standard.

Our Section Five cases, as they have evolved, have in fact tracked the safeguards standards, so that they are applied both one and the same. In addition to that, occasionally we use the Fair Credit Reporting Act, which is a subset of information. This is consumer report information. There are general requirements to ensure that reasonable security in terms of the appropriate access and also there's a specific provision dealing with disposal of consumer report information.

We have now brought a total of about 30 cases, which cover all types of personally identifiable information, in either electronic or paper form. By and large, these cases are negotiated settlements. They're generally not litigated. We usually bring this through an administrative process. However, all of our cases tend to relate a different and an evolving story. They're all closely watched by industry.

Importantly, our approach at the FTC is that we are not a complaint-driven agency. We look at personal information broadly. We don't look just at cardholder data. So we cover any consumer information including employee data.

The scope of the consent agreement is not just limited to the alleged violation. In appropriate cases, we do what we call fencing-in relief in our orders, so that if we find violations in certain areas of security, the scope of the order is to cover all of their information security practices. These orders are typically for 20 year periods. While we don't have civil penalty authority, under Section Five, civil penalties do attach if the respondent violates the terms of the order.

Also, our approach is not tied to specific technologies or standards. We understand that technology evolves very rapidly, so we don't—again, this is part of the scalable and flexible—we don't say you have to do X, and if you do X, then you're fine.

Importantly, the cases that we brought are not close calls. We understand that security is not perfect, that there will be mistakes. There will be times when information is breached, but what we're looking for is systemic problems. Our respondents have included credit card processors, a security software vendors, mortgage brokers and lenders, data brokers such as ChoicePoint and LexisNexis, a drug manufacturer, two pharmacy chains, and a PBM—this is the CVS Caremark case—and Rite Aid, which we did jointly with HHS, and a number of retail merchants such as BJ's Wholesale and TJX.

There are all types of sensitive information that's been exposed: financial information, credit card information, employment information, health information such as prescription information, social security, driver's license. We have a range of failures including electronic and proper disposal of paper documents and electronic devices not having an appropriate plan.

The cases span for several general principles. Businesses that make claims about data security should be sure that they are accurate. Businesses should protect against common technology threats. Businesses should know with whom they're sharing customer sensitive personal information. Our ChoicePoint case was a point to raise here where ChoicePoint sold 160,000 consumer files to identity thieves who were posing as clients. They did not have reasonable procedures in place to identify who their customers were. Businesses should not retain sensitive information that they don't need. This speaks to data minimization and retention—appropriate retention. Businesses should dispose of sensitive consumer information properly.

We talk about defense in depth, which means that you have a lot of redundancy in the system. You don't just do one thing and cross your fingers and hope that it works. We've also raised a number of other issues such as peer-to-peer problems where earlier this year, we announced 100 companies had been sent letters regarding the leakage of highly sensitive personal information of all kinds including health information on the peer-to-peer network. We've also identified other high risk areas, such as wireless—and that has been a part of similar cases—and the hard drives and photocopiers and in fax machines.

On the privacy front: Earlier this year, we did an Exploring Privacy roundtable series. We did three public events. The idea there is that we wanted to step back and look more broadly at our privacy and security framework and re-think what we should be doing going forward, given the nature of technology and the impact that it's had. The issues that we discussed were wide-ranging. We talked about consumer expectations and disclosures. We did a series on online behavioral advertising, which built on some workshops that we had done in 2007. We looked at information brokers, social networking, mobile computing, in particular, the growing impact of communication tracking, cloud computing, and health information and sensitive information generally. This, as you know, is a very rapidly evolving landscape, particularly with the migration of what is health information outside the traditional provider setting. In addition, there's a question as to, given the nature of what is going on in business models, what is health information now.

The common themes that emerged are: Number one: Tracking. Consumers do not understand the extent to which companies are collecting, using, aggregating, or assembling, storing, and sharing their personal information. This includes not only the digital information, which is now collected ubiquitously, but the combining of that information with offline information and then monetizing the data.

Second: Secondary uses of information. This is uses that are beyond what the consumer expects. Again, it's companies that want to retain and collect and monetize the data. They may not have an idea today, but they think they will down the road. Anonymity and de-identified data or the PII (personally identifiable) and non-personally identifiable data distinction with the ability to connect up individual bits of data, which in and of themselves are benign. You are now able to, with a high degree of validity, identify individuals. It calls into question whether or not there's such a thing as de-identified data or we should have this distinction between PII or non-PII in the law anymore.

Finally, disclosures: Disclosures don't work. There was a lot of emphasis on that in the „90s and earlier in the 2000s, but the proliferation of disclosures, the complexity of the disclosures, the legal language in them—people were flooded with them, didn't read them, couldn't understand them, didn't know what to do

with them, and there was a lot of hidden stuff in them. Disclosures are not dead, but they're not the Holy Grail. We can, through consumer research and testing, develop comprehensible and usable notices, but these should be used in a targeted matter and a more uniform way so information is provided to the consumer at the time the consumer needs it to make a decision. Also, there should be a standard way for the consumer to set her preferences including a simple and easy means for her to say no to sharing practices.

I see I've exceeded my time, and I appreciate your indulgence.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you so much. James?

James Golden – Minnesota Department of Health – Director
I'd like to thank the Workgroup for allowing me to come and tell you of Minnesota's experience in trying to oversee and regulate health information exchange activities in Minnesota. I have some slides, which might just help direct the conversation and provide a nice summary of what is in my written testimony as well.

First, I'd like to start with how we got there. Last year at about this time, Minnesota spent three months; we had a public workgroup that looked at developing recommendations on the oversight for health information exchange. That might seem like a short time, but you have to understand Minnesota's been working on eHealth issues for about five years and have developed quite a lot of community trust.

That workgroup developed some recommendations. We put those out for a 30-day public comment period, ultimately revised them based on the public comment, and then those recommendations served as the foundation for our legislation that we moved forward in the last legislative session. Our legislative session goes between February and May. Our legislation went through a wide variety of committees, and ultimately on May 13th, was signed into law.

Essentially what our law requires is it requires certification of anyone conducting health information exchange in Minnesota. Effective as of July 1, 2010, all organizations that provide HIE services for clinical, meaningful use transactions must apply for a certificate in order to operate in the state of Minnesota.

What was the general purpose of the law? What were we trying to accomplish? I think there are a couple of things. The law provides the commissioner of health wide authorities to essentially protect the public interest. So, at its heart, we're trying to protect the public interest. Our primary foundation for doing that is really transparency in the activities. So we want to really make sure that we have a transparent, open process moving forward, both for consumers as well as stakeholders.

One of the other things that we wanted to try to accomplish with the legislation is we really wanted to allow an open and free market. When we look at the types of HIE service providers that we have—we have community organizations. You have electronic medical record companies. You have large national companies that maybe specialize in types of transactions—we wanted to make sure that they all could be in the market; that the market could innovate. We do understand that this is an embryonic market and don't really pretend that we know what it's going to look like two, five, or ten years down the road. But nonetheless, we did want to have some requirements on that. As I say, people do need a certificate of authority in order to operate in Minnesota.

A couple of things that the law has within it and the law is included in your packet of materials for your reference. The first is we define a health information organization. Essentially, the way we envision a health information organization is as the hub of the exchange activities. So we anticipate that a health information organization is an organization that will provide all of the clinical meaningful use transactions that a provider would need to conduct in order to meet the meaningful use requirements.

We also recognize that there were entities who may not provide all of the meaningful use transactions, but they might specialize in one or more of the meaningful use transactions, and we wanted to include them in the law. They are defined as a health data intermediary for us, an HIO or an HDI; combined. If you have either of those, they are a health information exchange service provider.

The last bullet also highlights, for us, what is a particularly important point, is that our law does not regulate healthcare providers that are engaged in direct health information exchange. So if a clinic and a hospital are going to exchange with each other directly, that's excluded from our oversight activities.

What are we trying to accomplish with the law and what are we actually trying to regulate? The first is we wanted to have some common ground rules for the people that are providing these services. One of those ground rules is that we require connections and interoperability with each other, so all HIOs in the state of Minnesota are required by law to connect with all other HIOs. Additionally, anyone who is an HDI must connect with at least one HIO, and thereby provide its services to the entire network as well.

We also want to make sure that all of these organizations in the transactions that they're exchanging are adhering to the nationally recognized standards and certification so that they will be interoperable with each other, but also much more likely to be interoperable with our neighbor states and other states we might want to exchange with. Finally, we require that all organizations maintain strategic and operational plans that describe quite clearly how they are going to assist healthcare providers in meeting meaningful use and those documents need to be public.

Also not on the slide but one of the things that we also require is we do require EMAC certification or accreditation for these organizations. We think that helps to address some of the technical issues associated with the activities that they're performing.

Financial sustainability is a significant concern of ours, based on the experience around the country of HIE service providers. What we do require of all of our providers is that they provide a schedule of proposed charges as well as they provide a public accounting—kind of what they're doing with their financial activities. What do they anticipate to be their income and expenses, as well as their capital needs over the next three years? The HIOs, which form the hub of our exchange networks, are required to submit a rate plan and fee structures explaining how their charges work for their exchange activities. Those rate structures are subject to rate review and approval by the commissioner.

One of the things that we were trying to do with our law was to protect a wide variety of entities. One of the first that we wanted to protect were consumers. So one of the key protections that we wanted was to ensure that we were meeting Dr. Blumenthal's goal of ensuring that all patient information can flow across the entire continuum of care, across all settings of care without any real boundaries that might be there, and so we think our inner connection and interoperability requirement help to do that. We also wanted the regulation to provide public hearings that would allow consumers the opportunity to participate in the regulation and provide meaningful input to us in whether or not to improve these applications or to request additional requirements on the organizations that are applying.

Both HIOs and HDIs must demonstrate compliance with all state and federal privacy laws. This was a particular concern to our consumers. They need to have and demonstrate that they have adequate insurance, particularly liability insurance that might be appropriate for breeches. They also need to provide a description of how their complaint activities would work if consumers may have concerns with the services that they're offering.

We also wanted to make sure we could protect our healthcare providers. Certainly healthcare providers are very interested in understanding how they can meet meaningful use. Again, we're trying to stop from having a fragmented system so that no matter who they're connected to, their patient information can flow throughout the network. We want the service providers to have a strategic and operational plan so providers can understand how that fits into them. We want the service providers to tell how they're going to work with the safety net providers in making sure that HIE services are available to them. Then also,

the HIE service providers need to let our healthcare providers understand how they can participate in the operation of the exchange activities that are going on.

As I say, we do require the HIOs and HDIs to connect with each other. We require them to have a reciprocal agreement with each other. There's a number of things that need to be done within that. They need to have a mechanism to permit each other access to their record locator services. These are really a master patient index with a pointer to patient health records. We wanted to ensure that they didn't impede the secure transaction of meaningful use transaction.

Probably one of the more interesting aspects of our law is the HIOs and HDIs cannot charge each other for the exchange for meaningful use transactions when they are transmitted according to nationally recognized standards. So, if I participate in one particular HIO and you're participating in another HIO, my HIO can certainly charge me because I'm a member/participant in that, but when that transaction goes from my HIO to you, there can't be a charge for that. It's kind of like e-mail. I pay my Internet service provider, but we don't have to pay at every step along the way.

This was particularly important. Our provider community was deathly afraid that transaction fees would eat every dollar of savings that we could possibly get from the increased use of exchange. We do have some quality of standard services and these agreements are subject to review and approval by the commissioner of health.

I will quickly just go through the application process. Applicants must complete an application. The application is in the materials that I have provided to this workgroup. That application is then posted upon the Department of Health's Website for ten days to allow all people that are interested the opportunity to take a look at that. We then have a public hearing where the applicant presents their application and any interested stakeholder may ask questions or provide comments. We use a five person review panel to help direct that public hearing. That review panel is made up of a physician, a hospital, a other eligible provider, a non-eligible provider, and a consumer, and is chaired by the Department of Health.

We also have enforcement authority in order to enforce these activities. We have a wide variety of ability in how to enforce. So we can certainly do voluntary enforcement where we work with the person or entity that is out of compliance to come into compliance. We can issue cease and desist orders. If that doesn't work, we have the ability to issue monetary penalties of up to $25,000 per violation. In extreme cases, we can suspend or revoke a HIE service providers application.

The funding of these activities in oversight is done through fees upon the entities that are providing the services, and those are provided there. All of our information is included in your packet as well as on our Website. If you have questions, I would be more than happy to answer those later.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you. Doug?

Doug Fridsma – ONC – Acting Director, Office of Standards & Interoperability
Thank you. I'd like to thank the committee for inviting me to talk a little bit about the work that we've been doing at ONC to help coordinate a lot of the activities around standard development. So, this is going to be at the opposite end of the spectrum in terms of detail, but I think it's important as we think about coordinating mechanisms and governance that we have sort of that broad spectrum.

So, many of you have seen this before. This is our standards and interoperability framework that we have within the Office of the National Coordinator and within my office for interoperability and standards, that really tries to articulate the way in which we manage the lifecycle of standards and implementation specification. I'd like to use this as a framework or as an outline to kind of break up into chunks the various kinds of coordination that we need to support our standard development and implementation specification efforts.

So at the beginning of this framework, we have to develop use cases and we have to do functional requirements. This requires us to coordinate across subject matter experts to be able to do priority setting across a variety of different use cases and to engage the community to determine what's the next thing that we need to work on. We also have to be able to have some coordination at an operational level that allows us to figure out how to harmonize our various standards, to make choices between the different kinds of representations that we might use, and then make sure that we work with standards development organizations and others on a technical basis to make sure that we have consistency with the artifacts and implementation specifications.

We need to do versioning and code development coordination. This means that we have to make sure that we don't get mixed up with the different versions that we have. That we make sure that we maintain over time versions across the implementation specifications or the standards that we have.

We then have to make sure that we've got certification criteria in testing. We have existing structures that help us coordinate that now through our Federal Advisory Committee, the Standards Committee, and some of the regulatory rulemaking. Finally, we need to be able to participate in pilot projects including things such as in-hand exchange and make sure that we coordinate those activities and the use of the standards and the evaluation of the implementation specifications that we have.

So, I just want to kind of step through those briefly. When we talk about subject matter experts and priority setting, we really have to realize that our goal here is a bottom-up, use-case driven, that is driven by use cases and needs. So if you think about what we've tried to do with the NHIN Direct project, galvanizing the community to try to solve a particular problem and helping support that through the development of the use cases, implementation specifications, and actual, real-world testing.

We have this notion of a use case steward, which might be an organization or a person that really is responsible for shepherding this through the process. The use case development is focused on stakeholders. It needs to include all stakeholders. That means our federal advisory committees that are helping us around meaningful use, but it also has a broader range of folks; the standards and interoperability framework and certainly our office supports the VLER project, that's the Virtual Lifetime Electronic Record project, a White House initiative, to help support how veterans and returning military servicemen are able to exchange some information across both of the VA and the DoD information systems.

We have federal partners who have needs that are specific to the federal systems. We have to be able to support patient privacy and security experts as well so that we have all of those people represented at the time that we do use case development within this framework.

We have a couple of things that you can kind of think about. We have to have this notion of strategic prioritization and we need to be able to make sure that our goals are aligned so that we're all driving towards the same focus here. Within that, we need to be able to then pick what is the next thing to work on or what's the next priority for us to work on. It may be that we shift things around a bit because of our dependencies and that's important to have people that understand how dependencies might work from a technical perspective, as well as those people who understand the strategic priorities that go into the use cases that we take a look at.

When we think about standards and the operational and technical coordination, we can kind of take that previous diagram and we can flow it all the way down to all of the different aspects of the S&I framework. So that means we need to have use case teams that are doing a technical work. We have to have coordination with our specification development teams. We need to be able to, on a day-to-day basis, organize and govern those particular groups.

We've got, within the standards and interoperability framework, a concept of operation that articulates how all of these moving parts work together. I think the thing that's important to identify from this slide is that we have this notion of control points. That at different points in the process, we need to sort of pop up a level and make sure that we're on the right track, that we have the ability to check in and make sure

that either with our use case steward or with our stakeholders that we haven't gotten off track in terms of our development work as well. So that's an important aspect in which we need to be able to coordinate across all of the different activities that occur.

When we think about versioning the code and the development coordination, I only include this, not so much that I think a body like this or rulemaking should apply to this area, but we need to be able to leverage knowledge in the open source communities and support rapid, iterative, and open development. This means that we have to have check-in and check-out procedures. We have to have ways of coordinating the various teams that might be developing this and coordinate with both our use case teams and the certification and testing teams on either end. So when we think about the coordination that's required, not only do we need coordination at a very high level from strategic and policy perspective, but we need to drill those all the way down to the operational coordination using software development tools and the ability to manage the artifacts that come out of the work of doing standard and implementation specification development.

We also have to coordinate with the certification criteria and testing. I'm not going to spend a lot of time talking about this because this is primarily focused in our current mechanisms. We've gone through this with rulemaking and we certainly have mechanisms in place to be able to identify what those certification criteria are and coordinate with NIST and others to develop out testing infrastructures.

Within the NHIN exchange and other pilots, I think that's an area as well that I'm hoping that Michael Matthews will spend a little bit more time talking about as well. I don't want to go into great depth with this, but certainly Michael and I have been coordinating a great deal over the last couple of months in terms of standing up many of the coordinating processes that we have there as well.

Just to give you a sense for what on-boarding—or bringing people into the network—requires operationally, we need to do conformance testing against standards specification. So for tools like CONNECT, the software that we use to exchange information, has to have conformance to the existing standards and specifications within NHIN. There's also additional conformance testing, not just with meaningful use, but in a more highly constrained set of requirements that the NHIN, or the Nationwide Health Information Network, exchange requires. If we think about this, this may be sort of setting the stage for some of the challenges that we may have with certification of HITSP or other ways of providing coordination of information exchange.

In addition to just doing conformance to standards, we also have to do what's called interoperability testing. What I mean by that is we have to have scripts for how people exchange information so that if I send a request for information, I need to get an acknowledgement back and be able to then respond appropriately. So it's not just conforming to the standards, but stringing those kinds of functionality together to essentially have a conversation about how information exchange should occur or a negotiation, if you will. This is more challenging than just conformance testing, but automatic testing can help here and can help people kind of get on board with that.

Finally, the Nationwide Health Information Network needs agreements to operate in a particular way. So not only is there conformance to standards and the ability to exchange information using this interoperability testing, but we have to have agreement that defines certain behaviors that we expect for people who are part of the exchange. So the ... some of those behaviors, for example, breach notification, and so within the Nationwide Health Information Network, we use a contracting mechanism currently to provide that level of enforcement. You sign the contract, which obligates you then to be able to perform in certain ways with regard to breach notification and others.

So if we think about this, one of the things I think is really important, as we think about governance and coordination, is that the goal of the S&I framework is to get us in the sweet spot where we talk about focused collaboration. Where we don't have top down command and control that's sort of preface driven. We don't have a thousand followers blooming from the bottom and disorganization. But we want to have a consensus driven process that provides open collaboration that has these guiding principles around this focused collaboration that's driven by real business needs and the use cases that we have, that drives all

the way to real-world implementation and establishes a coordination mechanism across the entire spectrum of the S&I framework. So if you think about focused collaboration as being NHIN Direct galvanized communities added to the platform that we support with information exchange in the S&I framework, that's sort of what our target is.

Final thoughts: Just as interoperability is not one size fits all, coordination or governance is not one size fits all. So different parts of this S&I framework will require different coordination mechanisms. Not all aspects necessarily lend themselves to formal governance established through rulemaking. We need to be cognizant that we need to maintain flexibility in those things that require rapid response to changing needs.

So when we think about things—we've got strategic priorities. We've got certification to standards and implementation specifications. We've got operational coordination. We need to have some mechanism that all of this can be approved and moved forward for specific purposes.

So, with that I'll end, but it's important as we think about the whole scope of what we might have with coordinating mechanisms and governance. This piece needs to fit into that overarching governance. We have to be careful to make sure that we maintain sufficient flexibility that we can get the work done of that day-to-day operational need.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Thank you. Michael?

Michael Matthews – MedVirginia – CEO
These are the best of slots and these are the worst of slots. Just bring us home. I really appreciate all the insights I've been provided by my fellow panelists here and the speakers throughout the day. I think there've been a lot of rich takeaways that we can incorporate into our workgroup conversations. My written testimony is provided and I will not read through that. I would like to highlight a few things though for me to convey in terms of key message points.

First, Dr. Ondra mentioned there are two critical requirements in the Nationwide Health Information Network of our overarching strategy, and those being trust and standards. I … that there's a critical third element that be clinical value. That unless and until we get to the point where health information exchange is viewed as the standard of care and provision of medicine to the citizens of our country, I think we'll continue to go through these exercises. What if? What if the conditions were just right, we had the right financial incentives, the trusts were there? Then maybe one day, some day the flowers would bloom and we'd have health information exchange. I think all of those are necessary, but if we can achieve the clinical value, I truly believe that that is primary and all else is derivative. We will find ways to incent, to have the standards, to have the governance in place and the operations in place.

As far as how we get through this process, I look at this in terms of three different bucks. First is what's missing, second is what's broken, and third is what's working. We've heard a lot today about what's working. There have been some great examples at local, state, and federal levels of what is working.

I'd like to add to the conversation about what is working in the context of the NHIN exchange and the work that the Coordinating Committee in concert with ONC. As has been expressed, the Coordinating Committee drives its governance authority from the DURSA trust agreement, signed and bound by all of the participants at NHIN exchange. If the NHIN is a network of networks, then the Coordinating Committee could be viewed as a governance of governances in that we're also reflective of the work that is occurring by each of the individual participants. We are reliant, as in exchange, upon the appropriate governing principles and mechanisms at a participant level.

The Coordinating Committee is an incredibly dedicated group. I am very proud of how everyone has stepped up. They're always available, always participating. Jim Borland from the SSA was the first Chair of the Coordinating Committee and set a high bar in terms of leadership for this important group. I

believe that we are all committed individually and collectively to fulfilling the responsibilities, which are delineated in the many documents that you've seen throughout the course of the day.

We have grown to a point now where we have a number of parties, ten to be exact, with many, many more on the way. By various assessments, we might hit 50 within the course of the next 12 to 18 months after we get through the SSA participants, the … communities, and some of state level HIEs. It's not just numbers but a diversity of participants as well. So we are having everything from RHIOs to federal agencies to smaller participant organizations as well.

I'm glad Doug proceeded me to speak to the work of the ONC and the Operations Team. In any kind of governance considerations, governance and management or governance in operations, must work hand-in-glove. I feel like we've done that. But as we look to the future, that's an area that we'll continue to have to make sure we stay in sync with one another.

As I look forward to what are the needs moving from here, I focus on sustainability and scalability. I do not believe we're either sustainable or scalable in our current configuration. We haven't figured out in the health information economy exactly what the funding, what the support mechanisms are to support our creation. On the scalability side, we're already moving through some processes to make ourselves more scalable.

Today, the DURSA says that everyone who signs the DURSA and is a participant on the exchange has a seat on the Coordinating Committee. We recognize that very soon, the Coordinating Committee will be unwieldy as any kind of governance authority. So we are going through the process today of moving through a representational model, where we'll have classes and members ... represented. So we're trying to achieve the balance of having institutional memory and investment of these charter members who began, the first ten, as well as allowing for more of a representational model moving forward.

As I just said, we need to keep the scalability of governance in sync with the scalability of operations. That's something that Doug and I will continue to have a lot of conversations on how do we move together in a way that's mutually supportive. Third, hopefully, we will come out of this entire governance hearing process and governance development process with the elimination of the requirement that's in place today, which is that the NHIN participants have to have a federal partner to be part of the exchange.

Participation of the federal agencies is absolutely critical. I have so much appreciated our work with the Social Security Administration, and being the first to go into limited production, I could not have asked for a finer, more committed and dedicated partner than the SSA. Likewise, we've been very pleased with the work that we're doing with the VA and DoD and the VLER Initiative. Others will, no doubt, get the value of those kind of partnerships as we move forward in time.

But the federal agencies participation, to me, has two areas of critical importance. One is the data itself, the data that would be available to those caring for the wounded warriors in the case of VA, DoD, or the disabled patients in the case of SSA. So the data itself are critical. But as much as anything, the participation of federal agencies is a statement of the trust that the agencies have in the Nationwide Health Information Network. So there's value in the participation as well demonstration of trust.

My final point would be that at this ,,, point in the NHIN and HIE development, I believe that governance has more to do than just policy, regulatory, and oversight. I believe that there is a measure of leadership that's also called for today. We need to grow and nurture what we all believe is an essential development in the provision of healthcare, which is the ability to move clinical data around to the right person at the right time in the right format. I believe that the federal agencies along with those in the exchange along with, importantly, ONC as well can use the bully pulpit that is provided to be not just good governors, but also ambassadors and advocates for the work that we have in front of us. Thank you for your time.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director

Questions? While people are formulating questions, I have one for James. I was trying to skim through the law, and I couldn't determine what it means to operate at the exchange in Minnesota. So I'm in

Wisconsin. My servers are in Wisconsin, but the provider of this bit of data is in St. Paul, and the recipient is in Minneapolis. Am I operating in Minnesota?

James Golden – Minnesota Department of Health – Director
I think the answer to your question is yes. We don't care where you're located, but if you're providing or selling services to healthcare providers or other people inside of Minnesota who need to exchange transactions, you are operating in Minnesota.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So, let me just take that one step further. I've got my server in Florida and 99.9% of my patients are in Florida. Then one of them moves to Minneapolis, and there is an exchange of data between the service that's in Florida to that one physician who's taking care of that one patient who has now moved.

James Golden – Minnesota Department of Health – Director
I don't think I would think of it in quite the way that you're thinking of it as in the both sides. I think I would think of it more as if you think of an Internet service provider. So you have a connection to the Internet through your Internet service provider. That Internet service provider is offering me a connection to that particular network. So once they're offering that to me, they're selling their services inside the state of Minnesota, that is what constitutes operating in Minnesota. The fact that once I'm connected, I might send e-mails anywhere in the world, it doesn't make the Internet service provider that the person who I am sending e-mails to part operating in Minnesota.

So, I think the way that we have envisioned this is you have some type of legal entity—it might be a community non-profit. It might be in electronic medical record—they are offering a set of services to particularly healthcare providers, hospitals, and eligible professionals, saying that if you connect to us, we can connect you to the rest of the healthcare world and send transactions and receive them. So it is that connection to me as a Minnesota hospital or clinic or other eligible provider that is offering the service. That's what makes you operating in Minnesota, in our vision.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Laura.

Laura Adams – Rhode Island Quality Institute – President & CEO
I'm going to go back to the consumer whose words keep echoing in my head about the hoarding of their data. You have indicated that you have that commitment to Dr. Blumenthal's concept that many of us share about the idea that ensuring that health information follows the patient across the full continuum of care. Therefore you've required the HIO to connect with each other, and that's of course half the battle. The data has to get to the HIO. What are you thinking in terms of governance beyond making sure that you can make sure that the data follows the patient?

James Golden – Minnesota Department of Health – Director
Well, Minnesota has particularly protective privacy laws with regard to all health information. So we require patient consent for just about any movement of health information including treatment, except in cases such as emergency and other things. Generally speaking, I think most of the Minnesota community is really looking at a distributed model, so for most of the health information exchange service providers that are developing within the state, I don't anticipate that they would actually hold a lot of data. The data that they would have is more about where the transactions are going. I guess from that standpoint, we haven't really addressed that issue within the law. With regard to a particular patient's health information leaving their healthcare provider, going to a third party, being stored there, and that third party having a wide variety of the ability to use that data, I don't think that would be envisioned or permitted under Minnesota law that existed independent of our law here.

Laura Adams – Rhode Island Quality Institute – President & CEO
My question is specific to any potential requirement of providers to participate in the exchange. I keep worrying about my consumer that says, "I'm afraid that my data won't be allowed to go into the exchange."

James Golden – Minnesota Department of Health – Director
Two things on that front: Long before this law was passed last year, in 2007 there was a law passed in Minnesota that said all physicians, clinics, and hospitals are required to have an interoperable electronic health record by 2015. So Minnesota will require physicians and hospitals to have an interoperable health record. What Minnesota law does stop short of is actually requiring the exchange of the information, but we do believe that by that time, there will be adequate clinical value that's there.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Wes.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
James, just to check, I think earlier you said that directed exchange was exempt from the consent requirement. Is that right?

James Golden – Minnesota Department of Health – Director
No. I didn't say that. It's not exempt from the consent requirement. It is exempt from regulatory oversight. So if a particular clinic and hospital want to exchange directly with each other, they aren't using any type of third party entity to facilitate that exchange, we don't require them to be certified. Though we do anticipate that by 2013, that won't be adequate for meaningful use incentives either.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
You just made a fairly broad statement in response to Laura's question, or John's question, that virtually any motion of information required patient consent. So, for example, if I'm a physician and I send somebody to the storefront to have blood drawn, if that patient doesn't sign a consent form, then it can't be reported to me electronically? Is that correct?

James Golden – Minnesota Department of Health – Director
If it's not your lab, and the patient doesn't sign the consent form, you can't exchange patient information with another healthcare provider for treatment purposes under Minnesota law. That's an existing law in Minnesota since the mid „70s.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Is this … permission like HIPAA, where if someone doesn't give the permission, I don't have to treat him?

James Golden – Minnesota Department of Health – Director
I'm going to sort of … on that issue.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
John?

John Glaser – Partners HealthCare System – VP & CIO
I have a couple of questions, one for Loretta and a couple for James. My question for Loretta, you had made a statement about the difficulty of de-identification of records. Given where both health records and decision support systems will inevitably go soon incorporating lots of genomic signature information, I think your observation becomes increasingly pervasive. So my question to you is do you foresee a day when de-identification is utterly impossible?

Loretta Garrison – Bureau of Consumer Protection – Senior Attorney
Well, that is a terrific question. That's actually something that HHS is grappling with now because, of course, HHS in its HIPAA rule, has a de-identification standard that is at least ten years ago. They're now doing some brute testing on that to see of the standard still works. My understanding from Latanya Sweeney is that it doesn't. I think this is consistent with all the studies that we've had reported to us that have been aired in our public events, which is why I raised the question that we're grappling with.

If we want to step back and think much more broadly about an appropriate framework for looking at the privacy of personal information generally across all types of industries, then does this distinction that we've had in the law for such a long time between personally identifiable and non-personally identifiable make any sense anymore? I don't think that we can simply go and say, "Well, IP address: Is it or isn't it? Which bucket does it go in?" Because you're going to have that conversation constantly so we have not made a decision yet or actually come to any conclusions. We welcome any thoughts people have, but we do think that we need to think about this differently. Maybe it is that there is no such thing as de-identified or anonymized or non-personally identifiable information and we would have to treat all pieces of data, at least in a baseline way, in the same way, and then depending on the sensitivity of it, perhaps have enhanced protections.

John Glaser – Partners HealthCare System – VP & CIO
So, I want to tie it back quickly to governance, and then go to a different set of questions. So, from the governance perspective, some of the earlier testimony we had today about separate consent for treatment purposes of secondary use purposes and the New Mexico HIE focusing solely on treatment consent purposes initially, I think those kind of governance guardrails will largely be driven by just how realistic de-identification becomes with the evolution of particularly genomic information. So I think there's a pretty direct connection with how we conceive of governance and the distinction between primary use and secondary use.

My second set of questions is for James. You mentioned that there's no transaction fee between any of the HDIs and HIOs. So my two questions, and they're somewhat related: One is your experience so far in sustainability models if there's no transaction fees, and the second somewhat related question is how do you foresee covering all of the so-called white space of rural providers? Do you see them all eventually attaching to one HIO or HDI or another? What's your vision of how that plays out get complete coverage for the state?

James Golden – Minnesota Department of Health – Director
Well, the first question on the sustainability model, I don't know that Minnesota is any farther ahead than most states with regard to answering those questions. What I can tell you with regard to our healthcare community, particularly our provider community, is that they are very interested in a subscription-style model, particularly for the meaningful use transactions. So the idea would be I find either a health information organization that can cover my complete needs or some combination of health data intermediaries that meet my meaningful use needs. I pay my subscription fees to that particular entity, and then for those particular transactions, I can do what I need to to conduct my healthcare delivery for treatment purposes.

Now there are opportunities for value-added services, non-meaningful use transactions. We don't actually regulate the non-meaningful use transactions, though as that moves beyond, I think there are other opportunities. I think we have looked a lot at the administrative side, such as claims and eligibility verification and some of the requirements on clearinghouses in that area, and that has been what we have modeled this on.

With regard to how do we anticipate covering the entire state, we have been using our 3013 cooperative agreement with ONC to support a particular community-based entity that is working toward HIO status in Minnesota. We anticipate using them to have at least one mechanism for statewide coverage. That having been said, I do anticipate that there are going to be lots of options that are open to healthcare providers. Some of the EMR vendors are very interested in trying to facilitate this. I think for select services like e-prescribing, you have entities like Surescripts which are there, and so I think that what we really want to facilitate is that our healthcare providers that really get those combination of services that make the most sense for their business model, whether it might be their EMR community organization that they're involved in or some combination of best of breed types of exchange entities.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Mary Jo?

Mary Jo Deering – ONC – Senior Policy Advisor
… a two-sided question for Michael. In your written testimony on page five, you have a list of the overall key functions for the Coordinating Committee and on the prior page, four, while you talk about three in particular … dispute resolution: breach reporting and sanctions, etc. So the first side of the question is do you have a sense of, among these functions, which are the most highly valued by your participants? It may be that you don't. This isn't a test.

Michael Matthews – MedVirginia – CEO
Good question, Mary Jo, and thank you for both your question as well as your support for the Coordinating Committee. I think as much as anything, the functions around how we do what we do— We live and breathe what we preach, which is around trust and ensuring that the governance mechanisms that we have all vested in are, in fact—there's great care taken into the administration of those. I would say not one conversation that I know of was ever rubber-stamped through, was ever dismissed as unimportant. That's both a ... as well as a scalable challenge because we have in many respects been sort of carving new territory as we go.

So we weren't given a set of operating policies and procedures and said, "Go govern this thing." We've had to, somewhat, create this thing as well as then implement it and operate it on the other side of that. So I think once people have gone through the process, we're trying to be a large learning community where we're reflecting on the lessons learned, incorporating what it was liked, both sides of that process, with the new ventures coming in and trying to streamline that side of the process as well as from the governance standpoint, how can we make sure that we're doing things efficiently as well.

Mary Jo Deering – ONC – Senior Policy Advisor
Just to set the context for the second half, as you pointed out, it includes huge federal agencies—the very biggest—and you have one very small provider down in one relatively small community. Now you have MedVirginia, which is a good example of a RHIO, certainly a ... mature model, and I'd like you to put on your MedVirginia hat for just a minute and talk about—

MedVirginia works both downward and upward. So you reach down and you reach down into the community, and you reach upward to the exchange governance mechanism. So, is there anything that you think we need to know from that intermediary perspective about governance as the workgroup gives ONC guidance on how to set a national framework?

Michael Matthews – MedVirginia – CEO
I love the question. It's one that we think about a lot. Health information organizations—and I think your term would be HDIs—these intermediaries, they do not occur naturally in nature. We have to figure out ways to represent the interests of our multiple stakeholders. Everyone comes to the table seeking something different from their health information exchange.

The hospitals integrated delivery networks are looking for one set of value propositions out of it, the physicians, primary care, would look at one side of it, specialists would look at another. The labs, the rural providers, how we intersect with the wounded warrior community, the mental health community and so forth. Every single one has a different way of viewing what it is that we do. To me the challenge—regardless of whether we're dealing with a national, a local, a state, or at an organizational level—is where is the intersect of all those Venn diagrams? Making sure that we can articulate that, designate it, identify it, operate it, and then hopefully, there will be some conversion—there will never be complete conversion—but enough ground that people know what it is and have trust in the thing that it is.

So, I've talked about us being multilingual. We have to be able to speak lab, speak pharmacy, speak specialist, speak PCP, speak hospital, speak payer as we go through time on this and be able to say, "Come. Join the party. We understand what your needs are. We're there to help support you in partnering with others," because if we can kind of keep our eyes on the prize, and prove clinical outcomes and performance with hopefully improved safety and efficiency along the way, then that's something that we have to rally around.

I'll reference back, Laura, again, one of the simple rules that are immutable. If we keep our eyes on that prize, then everyone should be in that part of the Venn diagram of overlapping circles with that. So, I'd say that would be the biggest things is that an overall level, regardless of whether you're doing it at a RHIO or above or below.

Laura Adams – Rhode Island Quality Institute – President & CEO
I wanted to ask, in a way, the same question to Jim, looking at the state level, to look down and to look up, and I'm thinking of how you see yourself interfacing in terms of the authorities that you're exercising within the states, you just spelled out for us. But as you look upward and outward to Minnesota's part of the constellation—not just of other states entities, but truly a nationwide constellation, and thinking again in terms of governance and issues and problems—are there particular areas that you're already seeing where you know they're the thorniest? Where you can already see that you have a need? Do you have an ask of this workgroup and of ONC of what it could do for you?

James Golden – Minnesota Department of Health – Director
I think that the single largest issue that we have a need at the national or federal level for are clearly the standards and the specifications. We don't have the expertise to do those. We want to be able to be coordinated with the other 50 states in what the national government is doing.

You've talked a lot about privacy and security. I would actually split those. I don't consider those remotely the same. I consider security to be much more of a national issue. I think we have very good frameworks for best practices around security. I would like to see much more security standards coming from the top down.

Privacy is very much of a local issue, I think. I think that it is where people are engaged on that. I have seen a national trend toward coming closer to Minnesota. We appreciate that. When we see what's going on with some of the Tiger Team, we think that this is going to be an ongoing issue. It's very challenging. You aren't going to change the laws. The states are having a tough time making any changes, so I think that's an area that we would not see a lot of hope coming from the federal government on that, but I would say standards are our number one issue.

I think our other issue are to the degree that you have national players, whether they would be federal agencies or some type of national entities, one of the questions you will need to think about it how do they participate and connect to state infrastructures? How do the two regulatory oversight systems mesh together?

Laura Adams – Rhode Island Quality Institute – President & CEO
Full disclosure. I'm from Minneapolis, but that wasn't the reason we invited you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Deven?

Deven McGraw – Center for Democracy & Technology – Director
Loretta, I just want to make sure I understood your point about—and actually more that the rest of the people here who are listening, either here or on the phone—understand your point about disclosure, because in healthcare, sometimes disclosure means something else. Are you talking about the notice transparency, the notice and consent regime, and how well that has worked to protect privacy in the consumer?

Loretta Garrison – Bureau of Consumer Protection – Senior Attorney
Yes. Generally, I'm talking about the notice and choice regime that we've had, but I also want to pick up on a broader point. That is it's an overworked word and one that I personally don't like, but the concept of transparency. In other words, letting the consumer know what it is you do with their information, whoever you are. This is really very challenging because oftentimes companies really don't want their consumers to know. In fact, what they really want to do is stroke their consumers and let them know that everything is okay and everything's protected. Don't worry about it and have a nice day.

So, one of the things that we've done, actually, in the notice world is under GLD (the Gramm-Leach-Bliley Act), the several federal agencies got together and initiated a, I hate to say this, but I think it took about six years long, research project. We did it on our own initiative, because there was a lot of complaints about these financial privacy notices, to do consumer research and to come up with a notice that consumers could actually understand and be able to use. That means use to understand the practices and be able to compare practices across financial institutions.

There was a lot of pushback from the financial industry about what we were doing. A lot of them didn't like it. But it is now an option. It's voluntary. We have a regulation and it looks like companies are adopting it. So I think it's both what you provide to consumers that they can read and use, but it's also your willingness to step forward and let them know what you're doing.

Connected to that, because consumers are bombarded with so many disclosures and so many contexts, they don't really read them. They don't have time to read them. In fact, Lorrie Cranor at Carnegie Mellon did this study trying to gauge how many hours it would require on an annual basis for a consumer to read notices, and it was something like a couple of hundred. I mean, no ordinary consumer is going to do that. We're paid to do that. That's our job. But anybody on the street is not going to do that.

We need some way to standardize what the practices are to get them down to some sort of a consumer expectation level, at least at a minimum level. We need to be strategic about when we provide these notices so that it's at the point when the consumer has to make a decision or there's certain rights about which they're to be advised and need to make a decision.

Deven McGraw – Center for Democracy & Technology – Director
I just have a quick question for Dr. Golden about Minnesota. So it looks like this regime of certifying HIOs and the other three letter acronym that I've already forgotten, but I know it's in here— How is this oversight, which is probably the most we've heard from in terms of direct experience with governance and governance infrastructure today, how is this funded? Because there's a fair amount of work involved in overseeing that and managing it.

James Golden – Minnesota Department of Health – Director
The actual regulatory process is funded in two ways. As part of the application, we charge an annual fee to anyone who is operating as a health information exchange service provider. The policy work has been funded out of other base appropriations that we have, both from the state as well as grant funds from ONC. To the degree that we actually take an enforcement action, all of the enforcement monetary penalties go back into the program for the purposes of enforcement.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We're about at time, so maybe a couple of quick questions.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
just want to say that very often with these committees, what we're doing is trying to scan for some information. I've got to say, James, you win the prize. I think, the materials that you've provided—the laws, the forms, the examples—really, really helpful for just I think our deliberations generally. I don't know if to credit you or ONC with it, but I wish very often when we have a lot of these hearings that we could actually see the language on the tools that people are using to implement the policies we talk about at the abstract levels. Very, very helpful. So thank you.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
John?

John Glaser – Partners HealthCare System – VP & CIO
I thought that was really cool work, so I think what I'm curious about is how many other states are at that level of depth, so to speak? So you're going from slogans—this was all important. You know how to do

this kind of stuff, but there's no substance there—to this kind of process that is being put in place. So I'm just curious whether the other states—

The other thing I'm sort of curious about: You've got a core objective, it would appear, which is to protect the sender and recipient of this data from getting flimflammed by somebody. It's fundamental, which is great, but it's different from a learning system. It's different from five other things you might have wanted to go off and do. So are there other states that are this far along? If there are, do they have the same sort of core objective, which is make sure nobody jacks up the fees and follows the standards and all that other stuff?

James Golden – Minnesota Department of Health – Director
My sense of that is that the state of New York is very far along in their thinking on this. I think some of the comments that Rachel had— We've had a lot of conversations with her about what we've tried to accomplish, what we've done right, what we think we could have done better.

One of the things that has been very helpful for us is there is a group with ONC that's based on the National Governor's Association to get us together into regional groups. At our regional meetings, we had been discussing what we had been trying to do on oversight and governance to try to make the market just work better on exchange. Many states have been very interested in that and are following our experience. I think they're kind of letting us be the guinea pigs to see how things work, but I would say the states in our region are very interested in what we're doing.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I have one final question for Loretta. As I was listening to you, I had some difficulty understanding the borders of jurisdiction between you and the Office of Civil Rights and implementation and enforcement of HIPAA privacy.

Loretta Garrison – Bureau of Consumer Protection – Senior Attorney
We don't enforce HIPAA. We enforce Section Five of the Trade Commission Act. In the two cases that we brought jointly, it was a situation where there were pharmacies that were discarding intact non-electronic materials in publicly accessible dumpsters. This was happening first in Indianapolis where the investigative reporter found it. He actually went and dragged blue bags of materials out of dumpsters and went through it and then in a number of cities around the country. So this was a clearly a widespread problem. They were clearly HIPAA violations. So OCR was looking at this.

But in addition to that, there were representations that were made to consumers about the manner in which the information was protected. There was also employee data that was found dumped. HIPAA doesn't cover anything other than protected health information, so what we did is we used our two authorities—because HIPAA's not exclusive to jurisdiction, but rather we have concurrent jurisdiction—we used our two authorities to do the investigation.

At the end of the day, we have two complementary orders, but they are different in terms of scope. The HHS order covers disposal of information in a non-electronic form and it's only from the pharmacy. We cover all personal information, so that's a much broader term. It includes employee data. It includes front store information. So you go to a drug store, a CVS, you're not just getting a prescription. You may get food or household items and pay for them with a credit card. So HIPAA doesn't cover that. We do, and employee data.

We covered in electronic and non-electronic format. We also covered the entire pharmacy—again, the front store, as well as the PBM, the ...—and our order is for 20 years. It covers the handling of all information—the whole process, so it's not just focused on disposal. So we felt that in both of those cases, we were able to exercise our two authorities in conjunction. There was a certain synergy in being able to bring these actions against these particular companies.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
I thought there was a law about federal agencies not working together.

Loretta Garrison – Bureau of Consumer Protection – Senior Attorney
There is a law. Well, we do a lot of it, actually, at the FCC.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Carol? Do you have a follow-up?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Loretta, can you also just explain FCCs role in the personal health space?

Loretta Garrison – Bureau of Consumer Protection – Senior Attorney
I'm having a little trouble hearing you.

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
Sorry. I was just asking, just to round out your jurisdiction, can you also just explain the role in the personal health space?

Loretta Garrison – Bureau of Consumer Protection – Senior Attorney
Yes, thank you. That's a good point. HIPAA, of course, is a defined world because you've got providers basically who are covered, so as long as the information flows in this defined space, it's covered by HIPAA. But increasingly, as I alluded earlier, we're seeing a migration of that information outside into other companies that are not medical providers. So the personal health record vendors is a perfect example. Oftentimes, that information is transmitted through a third party, which is not a HIPAA covered entity, and then it gets to the vendor. In that case, it's going with consent, and once it's outside of that HIPAA environment, it's not HIPAA protected. I think most people don't realize that in fact, if they have a PHR with a vendor who is not a HIPAA covered entity, that HIPAA doesn't apply anymore. Our jurisdiction then takes over. So we have authority over those PHRs and under the HITECH Act, we have specific authority for data breach notice over PHR vendors and third party applications and any service providers.

But in addition to that, you've got a lot of online companies that are providing genetic testing information. I don't believe that those are HIPAA covered entities. They are going to be under our jurisdiction. You will also have situations such as Nike ..., who sell shoes to runners, and it's got a little RFD chip in it. It connects up to your iPod and it sends signals back to Nike with your running distance and time, I believe your heart rate, and the music that you're listening to. They have something like a couple of million users online. Well, is that health information? So there are more and more of these companies emerging that are collecting all kinds of information that we might have thought was traditionally health information, but it's all falling completely outside of the traditional provider environment.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So you get involved when companies tread on different fields. Okay. We're actually over time. I'd like to thank the panels. It was very enlightening. Michael, I did have a couple of questions for you, but I'll take care of them later. So, once again we'd like to thank you.

We'll now move into committee discussion. Mary Jo?

Mary Jo Deering – ONC – Senior Policy Advisor
....

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Okay. Whew! So let me summarize where we are in relationship to our task. We have had an initial meeting on phone call. We've put together a subgroup, which has been working diligently in trying to put together a straw person report for us to look at for our meeting on Monday. Then we have conducted today's hearings, the straw person group. I think John and Carol are the only two who are here from that. But I wanted to thank you for your weekly calls of working together with Mary Jo and—

Mary Jo Deering – ONC – Senior Policy Advisor
Michael is also on that.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Oh, and Mike. Thank you. So, that work, I think, is progressing very well. So you should be seeing something from there by the end of this week for our meeting on Monday.

So now at this point, we do have an opportunity to raise issues based upon our discussion from all four panels plus Laura's presentation on issues that we may want to make sure that at least will be addressed by the draft that subgroup is working on. Or any other ideas or impressions based upon the conversations today or not.

Deven McGraw – Center for Democracy & Technology – Director
Can I ask Laura a question? I didn't mean to put you on the spot earlier. I have been to the IOM meetings, but I'm still trying to figure out what we think is the likely outcome of that. Is it going to be terribly specific or a set of sort of broader principles to consider with respect to what it's going to take to create a learning healthcare system? As I said to you personally—this is not meant at all to be critical of that effort—I think one of the challenges when you take a step back and say, "We're not going to make any presumptions or assumptions. We're going to bring a bunch of people to the table who haven't been as active in these conversations and see where it goes." Then it goes in a lot of different places and it's really hard to figure out what it all means and what's going to be the outcome of all of that. Also, what's the timing given that this workgroup has a pretty strict timetable for coming up with recommendations of its own and there's a little bit of overlap, essentially?

Laura Adams – Rhode Island Quality Institute – President & CEO
I in no way take it as criticism. I think it is legitimate curiosity and real inquiry into how does this fit because you can blue sky things all you want. We still have to start with reality in many ways. There are a number of us that are engaged in things like this where we—imagine. You have questions. I really have questions and I'm chairing that in on this. So I think that the likely outcome of October 5—Is that next Tuesday?—is that, over the summer, this sense that we would come up with a set of principles, a set of strategic recommendations that would maybe form the basis of a strategic plan. I actually didn't get that sense at our last meeting, particularly as the discussions centered around ultra large scale systems, that there was more of this push to a pilot. A push to a sense of let's look at this architecture as potentially a break through architecture.

There was a lot of discussion around will architecture dictate the type of governance that you need? I would say that it was split. There were camps that said governance was governance, whatever the architecture. There were others who said no. If you have much more of complex adaptive systems type of an architecture, you have a very different governance structure than if you do if you're Surescripts, for example. Their architecture, in some ways, is closed. There is that element of they make the decision.

So I am not sure what will come out of next Tuesday. I would not be surprised if there was a path to a pilot that came out of it in addition to all those recommendations for potential strategy going forward. However, we're not unaware of our sponsor, ONC, so there is, to my knowledge, no funding going forward. That'll stop any effort pretty quickly, especially a very, very large scale, let's-include-everybody effort. My worry is that there will be a pocket that will get together and we'll have different pockets that have some sort of smaller elements of funding that may try to kick this off as kind of a pocket with some pennies. I worry about what that will mean eventually to the whole thing.

So it remains to be seen, but the effort is so intriguing and interesting to hear people talk about where they think we are now relative to what the technology enables. I went in sort of technology-agnostic, but they're beginning to make a believer out of me in terms of thinking through some of the implications for complex adaptive systems thinking applied to the whole ball of wax, including the technology. With that, speakers that have pointed out, "Look, the Internet's a great thing and it's enabled a tremendous amount of innovation." The greatest weakness of the Internet is privacy. Don't forget that. So, I don't know how

far some of these thoughts will go, but my sense is that they must converge at some point, and we have to have a collective conversation, which I have a lot of confidence ONC will make sure happens.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
As the keeper of process, I think that we should look at what the role of this workgroup is and that is to give our best recommendations to ONC within the timeframes that we have. This is not the sole input that ONC will have as they are developing the notice of proposed rulemaking, the NPRM. They're going to take all of this stuff and they're going to do their best shot at what an NPRM ought to look that. I think the work the IOM Committee and our work will enable others outside of ONC to say, "Okay, let's look at this NPRM. How close does it come to what seems to be some of the best thinking?"

I think when we conduct hearings about the NPRM in the second or third quarter of 2011, we will certainly pull back in some of the thoughts and learning from the IOM Committee as well as other sources as we try to then vet that role and make recommendations or make a comment during the comment period for that role. So, I think that even though they're on somewhat parallel paths, it's okay.

Laura Adams – Rhode Island Quality Institute – President & CEO
I was just going to say it harkens back to the principles. It's a both/and we keep coming up with. Anytime we're looking at an either/or, we're trying to apply the principle of how do we do both/and?

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Three comments that actually end up actually tying together: One, I'm trying to remember when the first IOM publication on ERAS came out, but we're getting pretty close to the 17-year rule, aren't we?

W
1999.

Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst
Oh. So we have got 5 more years before we get to the 17-year rule. Okay.

Two: I was able to go to one of your meetings, Laura, and came away with a recognition I think everybody in research really understood. That there are huge gaps between issues of consent and issues of having large cohorts of randomly selected patients. It was interesting to hear you talking about less rigorous study methods as one approach to that conflict today.

But, if there's one comment I heard all day that really struck me the most strongly, it is A: That NHIN governance is about governance of governances, and NHIN is a network of networks. B: It's very important that it be structured in a way that it be adaptable to problems such as the one that is coming out of IOM in the future. That is to say that if it is too narrowly confined to implementing meaningful use, to implementing the NHIN as conceived now, that it will not be a go forward platform for what we have coming.

I think those two things go together in the sense that the reduction of complexities—I won't say the simplicity, but the reduction of complexities—associated with it being a governance of governances leaves us more options to leave things open than we might otherwise have.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Chuck?

Chuck Friedman – ONC – Deputy National Coordinator
I thought today was terrific and all the panelists had some remarkable stuff to tell. Sort of basic overall conclusion: There is an amazing amount to learn here. So to agree Minnesota's the first state out with something like that and it's kind of neat that you can imagine this and imagine that. It's certain that it will take a while to understand whether that approach works, how well it does, and a variety of other things. There's also an amazing diversity of efforts that are out there.

So the conclusion for me is to be really light on the governance going into this thing and to be very careful of rules which have one of the things I've learned in my ONC days, is just the power of the things. Just be careful, and parsimonious at a level because it is just not clear how to run a bunch of these stuff and what authority to invest in rules, what authority to invest in the body, etc. So I think I would sort of keep it light without under doing it, etc., but be very careful about engineering things we really don't understand very well at all.

Part of it is, and I don't really know, and the rule people and Jodi, at all is the insurance that there is a focused way of learning, and that the issues that are brought before the Policy Committee, the Standards Committee, and I don't know quite how to—there are probably a variety of ways to set that up under a federal umbrella, but I think the ongoing learning—and at a focal point. There'll be lots of learning out and about, but a way by which that has really brought together for ongoing conversations of workgroups like this, or particularly the two FACAs that have been established because there is a lot to be absorbed. It will take a couple of years. I don't think it'll happen quickly.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Carol?

Carol Diamond – Markle Foundation – Managing Director Healthcare Program
So, I want to agree, John Glaser, this time, with what you're saying and also say that I think even in our little small workgroup, it's becoming more and more apparent to me—and it was certainly a theme we heard throughout the day—that one of the most important things now is to provide some level of coordination between all these things that are going on, both for learning but also because where there are overlaps or gaps or places where, gee, this sort of existing process is covering some part of the terrain, but there's another entity that thinks it's doing that also. I mean even that exercise and illuminating where there are really important membranes that need to be coordinated, I think, between the standards and policy and other places, is really an important task. It's not about, I think, yet creating something or saying there's a new thing, but in really seeing this as a governance of governance. In order to do that, there's a level of coordination, I think, that it's apparent from a lot of the messages that we heard today, but coordination is almost the most critical takeaway for me today.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
John?

John Glaser – Partners HealthCare System – VP & CIO
So, given the diversity of the testimony that we heard today, it is somewhat surprising to me how much convergence there is amongst us on the panel because I agree with all the summary comments that Laura and Wes and John and Carol have made already. The thing that really sort of tied it together the best for me was Laura's reference to complex adaptive systems and the need to have a few, simple organizing concepts to really manage. So if we accept the tenement that there's a lot more we don't know that what we do know, and we accept that we need to be parsimonious in how we move forward, it comes back to the discussion that we had at the very first meeting of this group, where we asked the question, what is it we must regulate? What are the levers that we have to pull? How do we pull those levers in a parsimonious fashion?

So what I'd like to add to what's already been articulated so well is that we may have a major task around the current expectation setting, because I think the NPRM sort of presumes that there's a solution. I think what we're all violently agreeing on is that there's an evolution rather than a solution and that the NPRM can, at best, be a point of departure, but that we need to institutionalize within that document the latitude and the flexibility to be able to evolve it. So that raises a question.

If we discover that there's a new lever that we need to pull and we don't have such a lever to pull, what latitude can be pertained by the processes established by the NPRM to introduce that lever and associated infrastructure? When is it necessary to go back to rulemaking in order to extend upon that point of departure? So, it just strikes me that maybe the most important language we put into the NPRM is about the evolutionary capability of the governance process itself.

W
… elements.

John Glaser – Partners HealthCare System – VP & CIO
And all its elements, yes because there's the whole derivative infrastructure that flows from certification to compliance to sanction to enforcement.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
So I'm going to be a little bit of a contrarian before I call on Laura, and say that the presentation from Minnesota scared me a little bit. I think about that because one of the areas that I work on a fair bit lately is issues related to the nursing workforce. There's such a great variation between what a nurse can do in Alabama and what a nurse can do in New York. It makes it very difficult for multi-state organizations to distribute staff and have them engage in reasonable activities. The fact that 50 states could have a much more detailed and aggressive way at how health data is exchanged could be a very chilling effect on exchange of data or development of entities that would, much as we've heard in other fields, where there's some consolidation of the industry and people are doing exchange in some sort of standardized way. Whether that's good or bad, we do know that multiple state variations can have a chilling effect on that exchange and so I think it's just something we need to think about.

Laura?

Laura Adams – Rhode Island Quality Institute – President & CEO
I do want to underscore that idea of just how much we don't know, and that I think this is where some of the principles of complex adaptive systems really do help us out in the sense of when we think of—probably Wes described it as not less rigorous types of research. It's differently rigorous. We're learning in a different way than we traditionally have. So to a certain extent, enabling some of that with a great fear—people are looking at metadata and saying, "Look. You never know the origin of that data." Drawing conclusions from that. Never knowing the quality of the data or who has providence over the data. So thinking through how to use these systems, how to make sure that we can maximize the use of it.

I think that we really have to build a system that is capable of some management of paradox. That knows how and understands that some of these things, we will never reconcile perfectly. We have to move forward anyway. So, we're trying to protect privacy to the extent that we can. We're trying to enable value to be derived from the data. That governance structure has to understand that there's going to be a number of paradoxes to manage here. That's not to concede that we'll never make everyone happy. We're not in the business of making everyone happy. I think we're in the business of making everyone healthy.

So to the extent that we can try to build something that, again, looking at things like that notion of providing direction without providing directive. If we can think about how that structure is built so that it permits the learning to go on.

My point is that I'd like to see us recommend that this governance structure have its own requirement for learning about its own behavior and its effect. I think that's what we're alluding to a little bit with this idea of also what's its meaning for certification? But very specifically.

I don't mean an evaluation of how well did we do? Did we stay in budget? I really want to see what effect did this have to the extent that we can understand? Did it enable the types of things that we were looking to enable? And to define those things ahead of time, so that we have some way— Not after a year of work, but over time, periodically, quarterly, semi-annually, to look at certain aspects of our work and find out earlier than a year into the governance structure whether or not it's moving in the right direction. We'll not have the exact answers, but I think directionally, we can determine that. So I would recommend that we build a very strong ability to learn from our own behavior. Those structures are sometimes hard to

build, but I think they're really essential for us, making sure we don't go far down a path that doesn't meet our objectives without knowing it.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Mike.

Michael Matthews – MedVirginia – CEO
I don't have a lot of time to contemplate this as I'm stuck on the beltway headed back to Richmond tonight. So, I wanted to share my pain with all of you. The thing that's troubled me most about this conversation is how much of a future tense we're using in all our discussion and not fully acknowledging exchange is happening today. That we're not starting from scratch. We've got a lot of things going on to build upon. So getting to Laura's both/and concept here, we certainly need to evolve. We need to make sure that our governance principles and operations are evolving along with the use cases, engagement of participants, and so forth.

But I think we're sending the wrong message to the public when we don't acknowledge that exchange is being carried out today at multiple levels, whether it's at an organizational level, a state level, even at a national level now with the engagement of the federal agencies and so forth. If I were just an outsider listening in to some of these conversations, I would think that, "Well, how is that happening today without the appropriate governance oversight?"

So, I just encourage us to, as we go through the process, to again go back to if it's broken, let's fix it. If it's missing, let's fill in the gap. Let's build upon what's working. I think we'll be able to bite off some of this work that's in front of us, not be overwhelmed by it, identify where are some priorities that are most important to us, but in a framework then that will allow the continued evolution as we move forward.

M
I think that was a really good reality check from Michael in terms of what's actually occurring today. The distinction I draw between present tense and future tense is similar to the distinction between exchange for treatment purposes using established mechanisms today. What lies ahead of us in two arenas in particular: One is the research arena and associated problems with de-identification. The second is around consumer-directed healthcare.

So, I know a lot of folks here are working on consumer-directed healthcare. I'm pretty intimately involved in building an infrastructure around that. When you play out the information flow that will happen in provider to consumer, provider to provider, provider to consumer decision support for consumer-directed healthcare and then look at autonomous machine to consumer, consumer-directed healthcare, and all of the information that becomes the substrate for both direct to provider and direct to consumer decision support; what it creates is an extraordinarily complex path for common information elements with some overlap and some elements that reside only in the provider side, some that reside only on the consumer side.

My point being that while, in the present tense, exchange is working, exchange is happening, I think our ability as a national oversight governance process to protect against adverse outcomes in information exchange that becomes as complex as all that, is going to make some of our current dilemmas look really, really easy.

Deven McGraw – Center for Democracy & Technology – Director
One thing occurs to me from John is that while there's information sharing that's going on today among providers and there's information sharing going on today with consumers and consumers sharing information without provider influence at all, I think we do have to be mindful of what it is we think we want to govern or should govern with ONCs set of policy levers. Because there's a section of that—the consumer piece in particular—that, while I don't want to sound naïve about the impact and the interconnectedness of that to the provider sharing, it is also the piece that I think those of us who have pressed really hard for consumers to have better access to their data so that they can go off and that there'll be a lot of innovation in that space that we just cannot predict today and that perhaps we shouldn't

attempt to necessarily oversee through this governance process. So I'll put that out there. I'm sure people will push back on me.

I guess part of why I put that out there is that I think that maybe we ought to, in fact, focus on the provider information sharing aspects of this. Making sure that patients do have access to that data so that then the innovative piece that I think a lot of us will expect when patients do have a greater ability to have and share their data will actually happen. So, cautionary tale there.

I think the other thing that I want to mention is to say that Leslie Harris, who is the head of CDT, who is officially the member of this workgroup, has been attending the previous meetings, so if this has already been said, my apologies. But when I pointed out the work that Minnesota had done, I realized that I neglected to talk about the enormous working governance that Michael and the early NHIN grantees had done and are still doing on governance and that that ought to be something that we ought to strongly look to when we think of governance of governance. Because certainly with respect to early models of NHIN, when NHIN was defined as a network of networks, which you all were doing with putting together the governance for that infrastructure. So we don't want to miss the lessons from that effort and in terms of leveraging that going forward.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Chuck?

??Chuck Friedman – ONC – Deputy National Coordinator
Just a very quick response. So, I agree with you, Deven, that there are parts of that that we don't need to regulate. That was I was trying to characterize is that to the extent that there's lots of PHI that will be generated in the consumer space that will pass into the provider space and then for the pass provider to provider. It's very difficult to isolate that because it's not going to be fully utilized information to the extent that it's not available to the provider. Once it's available to the provider, it's subject to all the same issues. So, yes. We shouldn't try and regulate the autonomous consumer-directed stuff directly, but indirectly, it's going to be very difficult to isolate that.

Deven McGraw – Center for Democracy & Technology – Director
Well, … comes in, it's information like any other information … the provider. Absolutely.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Mary Jo.

Mary Jo Deering – ONC – Senior Policy Advisor
I don't want to interrupt the substantive discussion, but when that's done, I wanted to add a quasi process comment.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
We also have public comments, so I wanted to remind people so that as we wind down, we have some things to do.

Mary Jo Deering – ONC – Senior Policy Advisor
It occurred to me that the full workgroup may not—it may have just been a … of mind meld, but the full workgroup may not know some of the decisions, a very fundamental decision of the small workgroup about the phased approach that we were going to take. It seems to me, before I say what the phased approach is, I'm going to preface it by saying, if anything, today's testimony, for me, confirmed the value of that approach.

So, the phased approach is you have two slices at the full HIT Policy Committee; one on the 20th of October, and one on the 19th of November, which has to be your final recommendations. Because there was this drum beat of interest in the workgroup, and as we've heard today, in— So what is it that really has to be done? What is it that's already being done? What are the gaps? Where are the possibilities? To really focus on that. Then, of course, there are the very substantive questions of what goes into the

NPRM, which is, okay. So, what is the governance that we would recommend? How exactly should it be implemented and who should implement it?

What the workgroup seems comfortable doing is setting aside in phase one and saving for phase two those last three questions and trying to get the workgroup's consensus around the what, the why, the what's there already, what's broken and needs to be fixed? Really, all the questions that I think we've heard now. I think it was also re-affirmed when John made his first presentation to the Policy Committee, which is a very summary presentation. Again, everybody was quite reasonably all over the board.

So I just wanted to say for the record—and I'm seeing heads nod—that there's comfort that you will not move directly to saying how it's going to be governed yet until you think everybody's on board with what needs to be governed. So that will be the focus of Monday.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Any other comments? John? I don't want to miss you because I've missed you so many times today.

Judy Sparrow – Office of the National Coordinator – Executive Director
At this point, we would like to invite the public, if you wish to make a comment, if you're in the room, please queue up to the mic. So, we'll wait a few minutes.

The meeting on October 4th, I think we've invited you all to come to Washington. It'll be in person, and I've got a room at the Humphrey Building at HHS, just a reminder. I know some of you can't make it, and I will give you a dial-in call number.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Did you say in the Humphrey Building?

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes. The Humphrey Building.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
As opposed to not in this hotel?

Judy Sparrow – Office of the National Coordinator – Executive Director
Correct. Right. So bring your photo ID to get into a federal building. We have nobody on the phone, nobody in the audience. I'll turn it back to Dr. Lumpkin.

John Lumpkin – Robert Wood Johnson Foundation – SVP & Director
Then we stand adjourned. Thank you.

Public Comment Received During the Meeting

1. I am enjoying this discussion. As a state HIT person, I can tell you that the greatest challenge is privacy and security. How will it occur among entities, among providers, across organizations and state lines? To a certain extent, we have discussed that it would make it easier for us if there were federal standards. But what we found in our environmental scan is that privacy officers are interpreting differently from one to another. Governance becomes easier when privacy and security issues are resolved. When people are not worried about the inadvertent disclosure of information that someone doesn't want disclosed, everyone is eager to share.